AF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	SETH, Pawan	Examiner:	WANG, Shengjun
Serial No.:	09/583,228	Group Art Unit:	1617
Filed:	May 26, 2000	Docket:	14577.0023US01
		Confirmation No.:	2041

Title: SUSTAINED RELEASE VERAPAMIL PHARMACEUTICAL COMPOSITION FREE OF FOOD EFFECT AND A METHOD FOR ALLEVIATING FOOD EFFECT IN DRUG RELEASE

TRANSMITTAL SHEET

23552
PATENT TRADEMARK OFFICE

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

We are transmitting herewith the attached:

- ☒ Transmittal Sheet in duplicate (w/fee authorization)
- ☒ Appellant's Brief on Appeal (in triplicate)
- ☒ Return postcard

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge Deposit Account No. 13-2725 in the amount of $500.00 for the Appeal Brief. Please charge any additional fees or credit overpayment to our deposit account if necessary. A duplicate of this sheet is enclosed.

Date: 3/17/2005

By: Ronald A. Daignault
Name: Ronald A. Daignault
Reg. No.: 25,968

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	SETH, Pawan	Examiner:	WANG, Shengjun
Serial No.:	09/583,228	Group Art Unit:	1617
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APPELLANT'S BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This Brief is presented in support of the Appeal filed on February 9, 2005, from the final rejection of Claims 1-4, 6, 9-14, 19-22 and 24-50 of the above-identified application, as set forth in the Office Action mailed September 9, 2004.

Please charge Deposit Account No. 13-2725 in the amount of $500.00 to cover the required fee for filing this Brief. A duplicate copy of the Transmittal Sheet is attached for this purpose.

A separate request for oral hearing with the appropriate fee will be filed within two months of the Examiner's Answer.

I. REAL PARTY OF INTEREST

The real party of interest is Teva Pharmaceuticals Curacao N.V. by way of an assignment from Biovail Laboratories Incorporated of January 7, 2005, filed for recordation with the U.S. Patent and Trademark Office on February 4, 2005.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-4, 6, 9-14, 19-22 and 24-50 are the pending claims in the present application and stand rejected. These claims are being appealed and a copy thereof is at the CLAIMS APPENDIX.

IV. STATUS OF AMENDMENTS

None.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The subject matter of the present invention as defined in claim 1 relates to a coated tablet free of food effect containing a core including 20-80% of active ingredient and 10-80% of a gelling agent with a coating including 30-80% of a gastroresistant polymer, based on the weight of the coating, and 10-40% of a hydrophilic silicon dioxide, where the polymer withstands the acidic medium of the stomach and duodenum, and dissolves in the intestine releasing the active ingredient, verapamil, without the influence of food intake.

The term "coated tablet" is in the specification at page 3, line 15. "Free of food effect" is first at page 2, lines 32-33 and also at page 5, lines 33-end of page. The "core" is first mentioned at page 2, line 37 then described in more detail with the active ingredient, verapamil, and the gelling agent at page 3, lines 16-36 which includes a description of compressing into tablets. The "coating" which represents the feature of the present invention is first disclosed at page 3, lines 1-4. A more detailed description is at page 4 and to line 3 of page 5. This description includes the important feature of the gastroresistant polymer, which is insoluble in acid but soluble at a pH above 5.5 which provides the release of verapamil in the intestine, as desired, rather than in the stomach or duodenum.

Claims 9 and 11 are independent claims similar to claim 1 but specifying particular gastroresistant polymers in the coating. The uncured poly(meth)acrylic acid polymer of claim 9 is disclosed at page 4, line 14, and the anionic copolymer of methacrylic acid and acrylic acid ethyl ester of claim 11 is disclosed also at page 4, lines 18-30.

Claim 26 is an independent claim similar to claim 1, with a further embodiment of providing an intermediate coating to the tablet. Such coating is described at page 5, lines 13-22.

Claims 35 and 43 are independent claims analogous to claims 9 and 11 and further containing an intermediate coating.

Working example 1 illustrates the "free of food effect" for the present tablet composition with carbamazepine as the active ingredient. Tablets containing verapamil are illustrated in working example 2.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-4, 6, 9-14, 19-22, 24-50 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (U.S. 5, 378,474).

Claims 26-50 reciting an intermediate coating stand separately rejected as obvious over Morella, above.

VII. ARGUMENT

A. Rejection of Claims 1-4, 6, 9-14, 19-22 and 24-50 under 35 U.S.C. 103(a) Over Morella et al. Should Be Reversed

(i) There Is No Motivation Nor Any Suggestion in Morella et al. to Appellant's Claimed Invention

The Morella *et al.* patent (Morella) describes a sustained release composition, which is a pellet or pellets compressed into tablets containing a core element and a coating. Col. 6, lines 12-21. The coating must be capable of slow release of drug in the stomach and faster release in the intestine. Col. 7 lines 13-18. The pellet composition is stated as not being compromised by food. Col.7, line 38. The coatings described are hybrid coatings which are tertiary systems, having at least one polymer which is substantially insoluble independent of pH, at least one enteric polymer which is substantially insoluble at acidic pH but at least partially soluble at a less acidic to basic pH, and at least one component which is at least partially soluble at acidic pH. Col.8, lines 38-62. Although Morella focuses on morphine as the active ingredient, the specification lists many drugs in columns 3-5 including verapamil.

In contrast to Morella, the present claimed invention are tablets made of a core, which is then coated. The tablets are prepared from compressing the active ingredient and a binder or granules therefrom. Pellets are not claimed nor described. More importantly, the coating essentially contains only one polymer, the enteric polymer, which is insoluble in acid media but soluble at a higher pH, thereby withstanding the stomach and duodenum and dissolving in the intestine releasing verapamil therein. Specifically, the coating contains 30 to 80% of the enteric polymer, based on the total weight, and 10-40% hydrophilic silicon dioxide.

In rejecting the pending claims, the Examiner pointed to claims 1, 2, 7 and 9 and Col. 4 in

Morella for finding the elements of Appellant's claims. However, claims 2, 7 and 9 are dependent on claim 1 and thus have the same limitations of the claims, which include only 1-30% of the enteric polymer, but more importantly, also require 1-85% of a matrix polymer, which is insoluble at pH 1-7.5 and additionally 1-60% of a compound which is soluble at pH 1-4. As described above, these are the elements of the composition taught by Morella. There is no suggestion nor any motivation to modify this composition and eliminate the other two components. "It is insufficient that the prior art disclosed the components of the patented device, either separately or used in other combination; there must be some teaching, suggestion, or incentive to make the combination made by the inventor." *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 15 USPQ2d 1321 (Fed. Cir. 1990), *cert. denied,* 498 U.S. 920 (1990). Here, the components of the instant invention are described in Morella in other combinations requiring additional components. The Morella reference should be considered as a whole, and portions teaching away from the claimed invention must be considered. See *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 USPQ 416 (Fed.Cir. 1986). In considering the Morella patent as a whole, it is clear that the present claimed combination is not taught, or suggested and that Morella does not provide motivation to modify his composition to the claimed composition of the present invention. This case is not about "optimization of amounts of ingredients to be employed in a composition". Appellant's composition is distinct from that of Morella.

(ii) Appellant Has Shown a Patentably Distinct Invention

Appellant's claims recite that the coating includes from 30 to 80% of a gastroresistant polymer soluble at a pH above 5.5. On the other hand, Morella teaches an analogous component at a level of 1-30%, preferably 2-20%.

In addition, the Morella patent requires the presence of an insoluble matrix polymer in its coating. Such a limitation is missing from Appellant's claims. As a result, the Morella composition has a different dissolution profile than the composition claimed by Appellant.

Dr. Pawan Seth, the inventor of the application on appeal, provided evidence in a Declaration under 37 C.F.R. §132 during the prosecution of Appellant's application which demonstrated the distinct formulations. A copy of the Declaration for the Board's conveninence is at Appendix A1.

Dr. Seth prepared two cores containing verapamil and a binder; one core was coated according to the present invention and the other according to formulation 3 in example 3 of Morella. The dissolution profiles were measured at a pH of 1.2 and at 7.5. At pH 1.2, the profiles were very similar whereas at pH of 7.5, marked differences were observed. Only 20% of verapamil was released after 18 hours from the Morella composition in contrast to over 70% in Appellant's composition. This comparison is clear evidence of patentably distinct compositions.

In the final rejection of September 9, 2004 in response to Appellant's arguments, the examiner does not see "significant" differences between what is disclosed in Morella and Appellant's claims. This seemingly is based on the fact that the insoluble polymer required in Morella is not excluded in Appellant's claims and that limitations from the specification are not read into the claims, citing *In re Van Geuns,* 988 F.2d 1181, 26 USPQ2d 1057 (Fed.Cir. 1993).

The *Van Geuns* case concerned the attempt to incorporate an NMR limitation into the claim. Here, there is no need to incorporate a limitation from the specification into Appellant's claims. Appellant's claimed tablet requires a coating having 30-80% by weight of the coating of a gastroresistant polymer and 10-40% of hydrophilic silicon dioxide. Appellant has pointed out in (i) above that such a coating is not suggested in Morella and, moreover, Appellant's composition, as shown by Dr. Seth, results in a markedly different dissolution profile at the desired pH to enable delivery of the drug into the intestine unexpectedly better than the Morella composition.

Appellant respectfully submits that the rejected claims are patentable over Morella.

B. <u>Claims 26 – 50 Are Separately Patentable Over Morella</u>

Claims 26-50 recite an intermediate coating between the core and the outer coating containing 30-80% of a gastroresistant polymer based on the total weight of the coating and 10-40% of hydrophilic silicon dioxide. These claims appear to have been separately rejected over Morella as an alleged "obvious alternative".

The examiner based his rejection on the erroneous assumption that two steps instead of one is obvious "(i.e. coating two time with the same material)". Appellant's specification defines the intermediate coating as a protective layer containing conventional excipients, page 5, lines 13-22. The intermediate coating is not the same as the outer coating. Morella is silent on using an intermediate coating. Thus there is no suggestion or motivation to add such a coating .

Accordingly for the reasons presented in A over Morella and the lack of any suggestion from Morella to insert a protective layer into Appellant's composition, claims 26-50 are separately patentable over Morella.

SUMMARY

In view of the above arguments and the evidence of record, Appellant's claimed invention is distinct from and unobvious over the Morella patent. The Morella patent does not suggest nor motivate one skilled in the relevant art to make the composition as claimed in the present application.

It is earnestly requested that the Examiner's rejection be reversed, and that all of the pending claims be allowed.

Please charge any additional fees or credit overpayment to Merchant & Gould Deposit Account No. 13-2725.

Respectfully submitted,

Date: 3/17/2005

By: _____
Name: Ronald A. Daignault
Reg. No.: 25,968

MERCHANT & GOULD P.C.
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CLAIMS APPENDIX

1. A tablet composition free of food effect comprising:

a) a core comprising from 20 to 80% by weight of verapamil and from 10 to 80% by weight of a gelling agent; and

b) a coating comprising, based on the weight of the coating, from 30 to 80% of a gastroresistant polymer, and from 10 to 40% of a hydrophilic silicon dioxide,

wherein the gastroresistant polymer will dissolve in the intestines while withstanding the acidic medium of the stomach and duodenum, and as the gastroresistant polymer dissolves, verapamil is released in the intestines without the influence of food intake.

2. A composition according to claim 1, wherein the gastroresistant polymer is selected from the group consisting of uncured poly(meth)acrylic acids, cellulose phthalates, alkylcellulose phthalates, an anionic copolymer of methacrylic acid and acrylic acid ethyl ester, and combinations thereof.

3. A composition according to claim 1, wherein the coating further comprises from 5 to 30% by weight based on the total weight of the coating of a plasticizer selected from the group consisting of polyethylene glycol, stearic acid, dibutyl sebacate, propylene glycol, triethyl citrate, and combinations thereof.

4. A composition according to claim 1, wherein the coating represents from 0.5 to 6% by weight of the core weight.

5. (Cancelled)

6. A composition according to claim 1, wherein the core comprises granules compressed together.

7. (cancelled)

8. (cancelled)

9. A tablet composition free of food effect comprising:

a) a core comprising from 20 to 80% by weight of verapamil and 10 to 80% by weight of a gelling agent;

b) a coating comprising, based the weight of the coating, from 30 to 80% of uncured poly(meth)acrylic acid polymer, and from 10 to 40% of a hydrophilic silicon dioxide,

wherein the uncured poly(meth)acrylic acid polymer will dissolve in the intestines while withstanding the acidic medium of the stomach and duodenum, and as the poly(meth)acrylic polymer dissolves, verapamil is released in the intestines without the influence of food intake.

10. A composition according to claim 9, wherein the coating further comprises from 5 to 30% by weight based on the total weight of the coating of a plasticizer selected from the group consisting of polyethylene glycol, stearic acid, dibutyl sebacate, propylene glycol, triethyl citrate, and combinations thereof.

11. A tablet composition free of food effect comprising:

a) a core comprising from 20 to 80% by weight of verapamil and from 10 to 80% by weight of a gelling agent; and

b) a coating comprising, based on the weight of the coating, from 30 to 80% of an anionic copolymer of methacrylic acid and acrylic acid ethyl ester, and from 10 to 40% by weight of a hydrophilic silicon dioxide,

wherein the copolymer will dissolve in the intestines while withstanding the acidic medium of the stomach and duodenum, and as the copolymer dissolves, verapamil is released in the intestines without the influence of food intake.

12. The composition according to claim 1, providing effective release of verapamil for a period of at least 8 hours.

13. The composition according to claim 9, providing effective release of verapamil for a period of at least 8 hours.

14. The composition according to claim 11, providing effective release of verapamil for a period of at least 8 hours.

15. - 18. (cancelled)

19. A composition according to claim 1, wherein the gelling agent is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, xanthan gum, carbomer, carragheen, polyethylene oxide, and combinations thereof.

20. A composition according to claim 9, wherein the gelling agent is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, xanthan gum, carbomer, carrogheen, polyethylene oxide, and combinations thereof.

21. A composition according to claim 11, wherein the gelling agent is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, xanthan gum, carbomer, carragheen, polyethylene oxide, and combinations thereof.

22. A composition according to claim 1, wherein the gastroresistant polymer is soluble at a pH above 5.5.

23. (cancelled)

24. A composition according to claim 11, wherein the copolymer is soluble at a pH above 5.5.

25. A composition according to claim 9, wherein the uncured poly(meth)acrylic acid polymer is soluble at a pH above 5.5.

26. A tablet composition free of food effect comprising:

a) a core comprising from 20 to 80% by weight of verapamil and from 10 to 80% by weight of a gelling agent;

b) an intermediate coating; and

c) a coating comprising, based on the weight of the coating, from 30 to 80% of a gastroresistant polymer and from 10 to 40% of a hydrophilic silicon dioxide, wherein the gastroresistant polymer will dissolve in the intestines while withstanding the acidic medium of the stomach and duodenum, and as the gastroresistant polymer dissolves, verapamil is released in the intestines without the influence of food intake.

27. A composition according to claim 26, wherein the gastroresistant polymer is selected from the group consisting of uncured poly(meth)acrylic acids, cellulose phthalates, alkylcellulose phthalates, an anionic copolymer of methacrylic acid and acrylic acid ethyl ester, and combinations thereof.

28. A composition according to claim 26, wherein the coating in c) further comprises from 5 to 30% by weight based on the total weight of the coating of a plasticizer selected from the group consisting of polyethylene glycol, stearic acid, dibutyl sebacate, propylene glycol, triethyl citrate, and combinations thereof.

29. A composition according to claim 26, wherein the coating in c) represents from 0.5 to 6% by weight of the core weight.

30. A composition according to claim 26, wherein the intermediate coating comprises hydroxypropylmethylcellulose and polyethylene glycol.

31. A composition according to claim 26, wherein the core comprises granules compressed together.

32. A composition according to claim 26, providing effective release of verapamil for a period of at least 8 hours.

33. A composition according to claim 26, wherein the gastroresistant polymer is soluble at a pH above 5.5.

34. A composition according to claim 26, wherein the gelling agent is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, xanthan gum, carbomer, carragheen, polyethylene oxide, and combinations thereof.

35. A tablet composition free of food effect comprising:

a) a core comprising from 20 to 80% by weight of verapamil and from 10 to 80% by weight of a gelling agent;

b) an intermediate coating; and

c) a coating comprising, based on the weight of the coating, from 30 to 80% of a uncured poly(meth)acrylic acid polymer and from 10 to 40% of a hydrophilic silicon dioxide,

wherein the polymer will dissolve in the intestines while withstanding the acidic medium of the stomach and duodenum, and as the polymer dissolves, verapamil is released in the intestines without the influence of food intake.

36. A composition according to claim 35, wherein the coating in c) further comprises from 5 to 30% by weight based on the total weight of the coating of a plasticizer selected from the group consisting of polyethylene glycol, stearic acid, dibutyl sebacate, propylene glycol, triethyl citrate, and combinations thereof.

37. A composition according to claim 35, wherein the coating in c) represents from 0.5 to 6% by weight of the core weight.

38. A composition according to claim 35, wherein the intermediate coating comprises hydroxypropylmethylcellulose and polyethylene glycol.

39. A composition according to claim 35, wherein the core comprises granules compressed together.

40. A composition according to claim 35, providing effective release of verapamil for a period of at least 8 hours.

41. A composition according to claim 35, wherein the uncured poly(meth)acrylic acid polymer is soluble at a pH above 5.5.

42. A composition according to claim 35, wherein the gelling agent is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, xanthan gum, carbomer, carragheen, polyethylene oxide, and combinations thereof.

43. A tablet composition free of food effect comprising:

a) a core comprising from 20 to 80% by weight of verapamil and from 10 to 80% by weight of a gelling agent;

b) an intermediate coating; and

c) a coating comprising, based on the weight of the coating, from 30 to 80% of an anionic copolymer of methacrylic acid and acrylic acid ethyl ester and from 10 to 40% by weight of a hydrophilic silicon dioxide,

wherein the copolymer will dissolve in the intestines while withstanding the acidic medium of the stomach and duodenum, and as the copolymer dissolves, verapamil is released in the intestines without the influence of food intake.

44. A composition according to claim 43, wherein the coating in c) further comprises from 5 to 30% by weight based on the total weight of the coating of a plasticizer selected from the group consisting of polyethylene glycol, stearic acid, dibutyl sebacate, propylene glycol, triethyl citrate, and combinations thereof.

45. A composition according to claim 43, wherein the coating in c) represents from 0.5 to 6% by weight of the core weight.

46. A composition according to claim 43, wherein the intermediate coating comprises hydroxypropylmethylcellulose and polyethylene glycol.

47. A composition according to claim 43, wherein the core comprises granules compressed together.

48. A composition according to claim 43, providing effective release of verapamil for a period of at least 8 hours.

49. A composition according to claim 43, wherein the copolymer is soluble at a pH above 5.5.

50. A composition according to claim 43, wherein the gelling agent is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, xanthan gum, carbomer, carragheen, polyethylene oxide, and combinations thereof.

EVIDENCE APPENDIX

A. OFFICE ACTIONS AND AMENDMENTS/RESPONSES

1. Declaration Under 37 C.F.R. §1.132 of Pawan Seth dated October 4, 2002 attached with Response filed October 24, 2002.

B. REFERENCES RELIED UPON BY THE EXAMINER

1. U.S. Patent No. 5,378,474

C. CASES CITED IN THE BRIEF

PAGE

A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	09/583,228
Filing Date:	May 26, 2000
Applicant:	Seth
Group Art Unit:	1615
Examiner:	M. Bahar
Title:	SUSTAINED RELEASE VERAPAMIL PHARMACEUTICAL COMPOSITION FREE OF FOOD EFFECT AND A METHOD FOR ALLEVIATING FOOD EFFECT IN DRUG RELEASE
Attorney Docket:	8674-000004

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Declaration Under 37 C.F.R. § 1.132 of Dr. Pawan Seth

I, Pawan Seth, declare as follows.

1. I hold a PhD in Pharmaceutical Technology – 1986 – from University Louis Pasteur, Strasbourg (France). I subsequently worked as Director of Research and Development, Quality Assurance in Mepha (Basel, Switzerland) until 1994. I am skilled in the development of
   - Controlled release products in multiparticulate units and single oral units.
   - Delayed release products.
   - Therapeutical Transdermal Systems.
   - Colon Delivery products.
   - Bioavailability enhancement.
   - Semi solid topical products

2. I am the co-founder of PharmaPass LLC, the present assignee, where PharmaPass is specialized in designing new galenic formulations for various drugs.

3. I am named as an inventor in 17 granted US patents. I am an inventor of the instant invention.

4. I have read and understood the Morella reference cited in the course of the examination of the instant invention. I have carried out tests to show the superior results of the composition presently claimed versus the Morella formulation.

5. Tablet compositions were manufactured according to the following table.

Ingredient	Core	Invention	% (coating)	Morella	% (coating)
Verapamil HCl	240.00				
Methocel Pr K100LV CR	15.00				
Methocel Pr K15M CR	40.00				
Avicel PH 101	25.00				
Plasdone K29/32	20.00				
Aerosil 200	1.50				
Magnesium Stearate	3.50				
Isopropyl Alcohol 99% USP	42.00				
PEG 1450		1.44	12		
Dye Blend Yellow DB1770		0.11	1		
Eudragit L 30 D-55		7.03	58		
Syloid 244 FP		2.80	23		
Triethyl Citrate		0.72	6		
Purified Water		80.00			
PEG 1450				2.14	18
Diethyl Phthalate, USP/NF				0.86	7
Ethocel 10 STD Premium				4.09	34
Eudragit L 100				0.91	8
Talc (Lo Micron)				4.00	33
Ethyl Alcohol 200 Proof				114.00	

Column 2 shows the ingredients of the core. The core is manufactured according to the instant patent application. Column 3 shows the ingredients of a coating according to the current invention. This coating is manufactured and deposited on the core according to the instant patent application. Column 5 shows the ingredients of a coating according to the Morella patent. Eudragit L100 is a 1:1 methacrylic acid: acrylic acid ethyl ester copolymer. The Morella coating corresponds to formulation 3 of column 14 of the Morella patent, with the amounts in Morella being divided by approximately 22 to arrive at the ingredient levels in the Table. The Morella-type coating is manufactured and deposited according to the Morella patent. Columns 2 and 4 give the corresponding percentages by weight of the individual ingredients in the coatings.

6. The in vitro dissolution profiles have been determined using the method disclosed in the Morella patent (USP Buffer pH 7.5 and pH (0.1 NHCl), basket 50 rpm).

7. Annex 1 gives the results at pH 1.2. At this pH value, both polymers of the coatings are insoluble; hence the respective dissolution profiles of the coatings are similar.

8. Annex 2 gives the results at pH 7.5. In this case, the dissolution profile of the composition of the invention is similar to the prolfile of the core, while the dissolution profile of the Morella composition is quite different. In this case, the polymer used in the invention is soluble, while the one of Morella is not. Note that the Morella patent shows a profile similar in both conditions.

9. These results show that the compositions of Morella and of the invention are different and will exhibit different behavior in the gastrointestinal (GI) tract. In the acidic medium of the stomach, both compositions will behave similarly. But the Morella composition will not substantially dissolve in the intestines (where pH is higher, typically above 5.5) while the composition of the invention will. This will provide distinct effects.

10. The coated formulation of the invention has different profiles at different pH. At pH 1.2, the formulation of the invention does not start to release the drug till about 4 hours, while at pH 7.5 the drug starts to release after 30 minutes. In order to avoid the food effect and still get very effective amount absorbed, the drug needs to be released in the intestine, which is achieved by the formulation of the invention. In contrast, the Morella formulation simply slows the release of the drug throughout the GI tract. It shows no difference in the release of the drug in the stomach or the intestine.

11. The release profile from the Morella formulation indicates that very little drug will be absorbed in the body. Since the drug released in the body is only about 20% after 18 hours, it actually does not avoid the food effect, but the difference in the fed and non fed conditions can not be detected. For example, if there is 30% food effect (difference between fed and fasting absorption), 30% of 20% = 6 % of the total is insignificant, but this is not because of avoiding the food effect – it is because of the poor drug absorption.

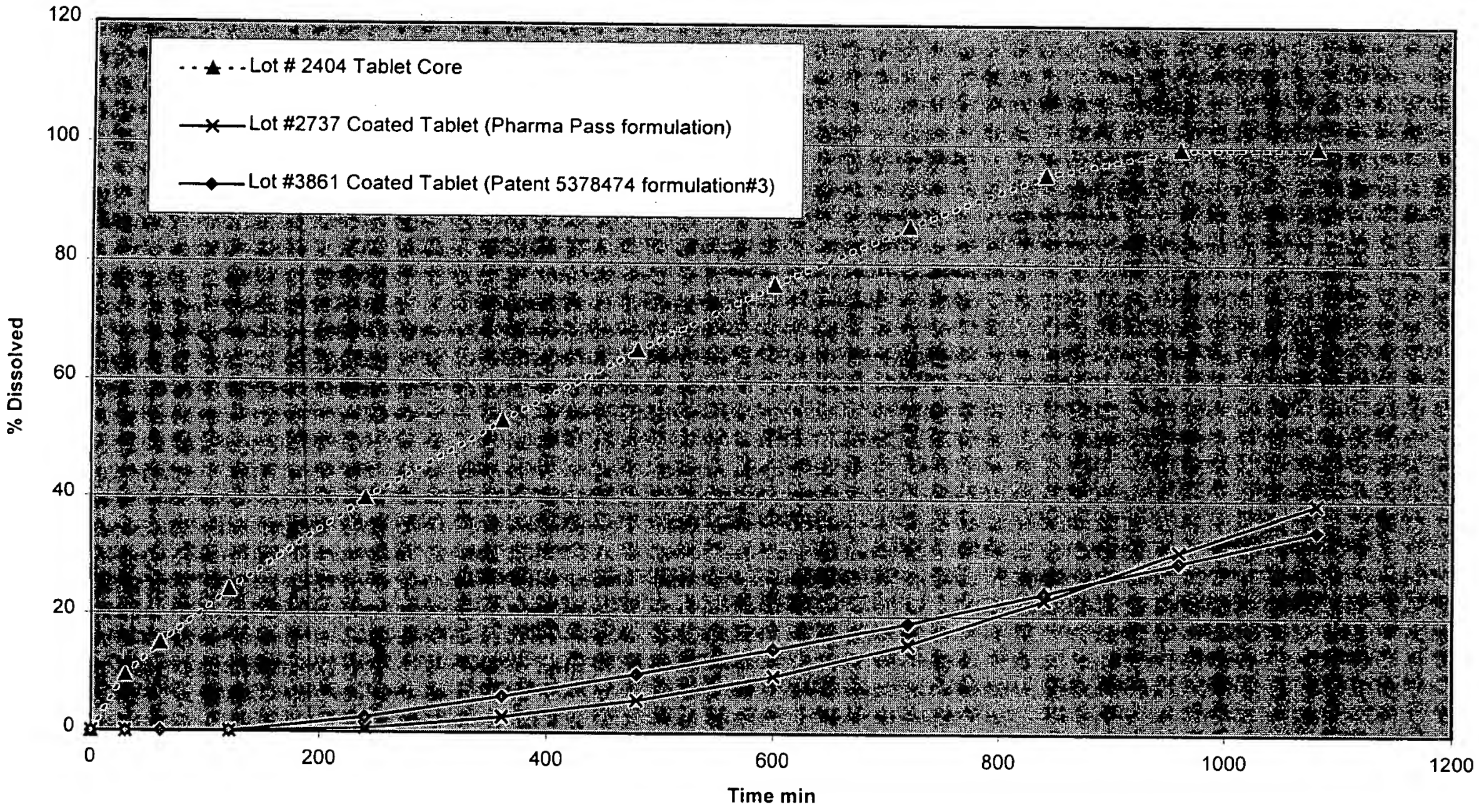
12. All statements made herein of my own knowledge are true. All statements made herein on information and belief are believed to be true. These statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonable, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.

4, Oct. 2002
Date

Pawan Seth
Pawan Seth

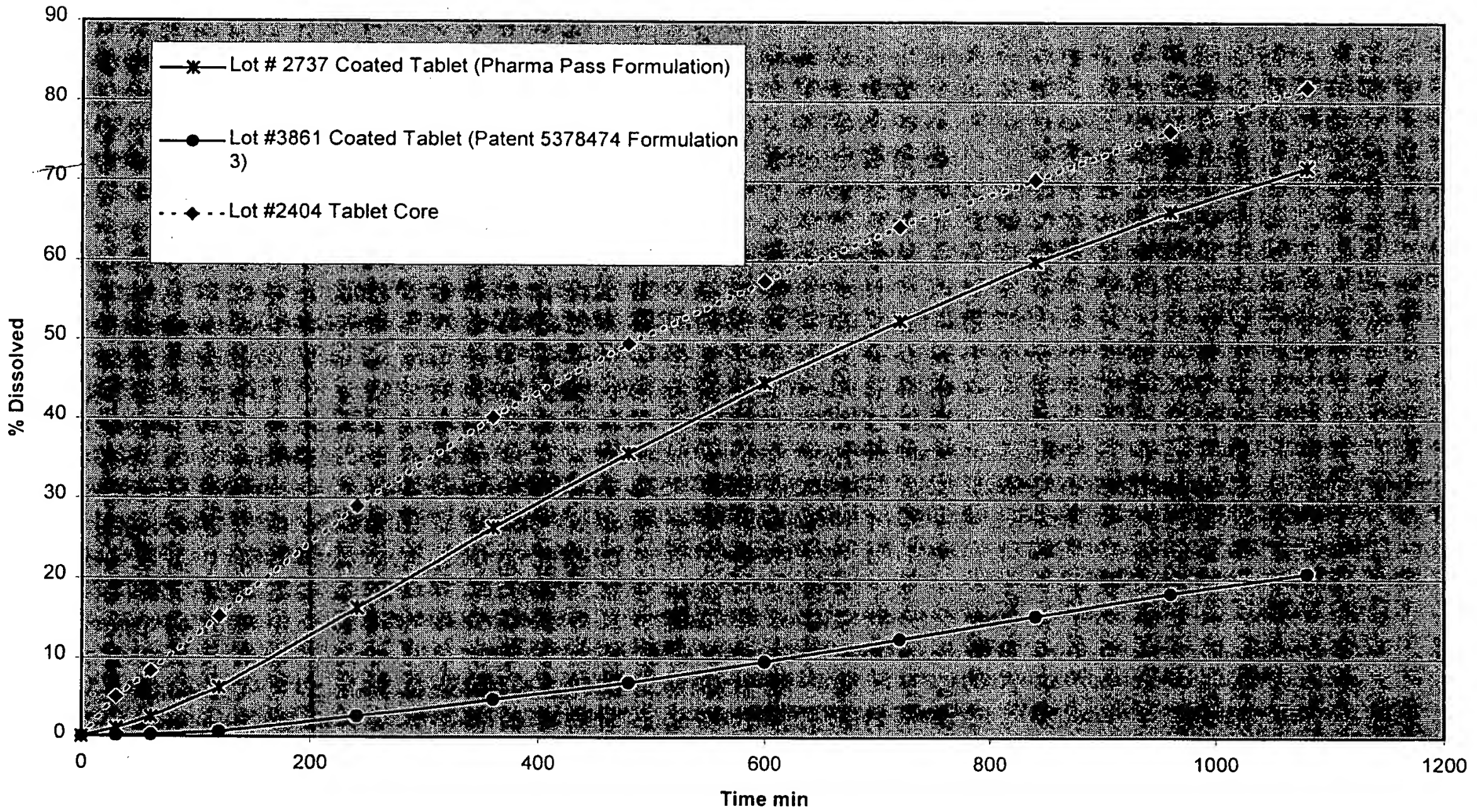
Annex 1

Verapamil In Vitro Dissolution pH 1.2 Basket 50rpm



Annex 2

Verapamil In Vitro Dissolution pH 7.5 Basket 50rpm



C

LEXSEE 908 F2D 931

NORTHERN TELECOM, INC., Plaintiff-Appellant, v. DATAPOINT CORPORATION, Defendant/Cross-Appellant

Nos. 89-1034, 89-1035

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

908 F.2d 931; 1990 U.S. App. LEXIS 10950; 15 U.S.P.Q.2D (BNA) 1321

June 29, 1990, Decided

SUBSEQUENT HISTORY: [**1]

Rehearing Denied August 27, 1990. Reported at: *1990 U.S. App. LEXIS 15192.*

PRIOR HISTORY: Appealed from U.S. District Court for the Northern District of Texas; Judge Fitzwater.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff appealed the judgment of the U.S. District Court for the Northern District of Texas declaring certain patent claims invalid and declaring the patent unenforceable. Defendant cross-appealed the district court's judgment holding certain patent claims valid and certain claims infringed.

OVERVIEW: Plaintiff's patent related to a mode of batch processing of data. Plaintiff filed suit and charged defendant with infringement. At issue on appeal was the enforceability of plaintiff's patent and the infringement by defendant. The court held that plaintiff's patent was not invalid for lack of enablement because the great weight of the testimony on both sides established that a programmer of reasonable skill could write a satisfactory program with ordinary effort. Thus, the programs involved here were routine to a skilled programmer. In addition, the court held that defendant failed to show that the circumstances of this case showed prejudicial error, or exceeded the trial court's discretionary authority. The court determined that the exclusion of the source codes was not grounds for reversal or other remedial action.

OUTCOME: The court reversed the district court's judgment holding plaintiff's patent invalid for failure to comply with the enablement requirement and determining the patent unenforceable based on inequitable conduct; however, the court affirmed the district court's judgment in all other respects.

LexisNexis(R) Headnotes

Patent Law > Anticipation & Novelty > General Overview

[HN1] It is insufficient that the prior art disclosed the components of the patented device, either separately or used in other combinations; there must be some teaching, suggestion, or incentive to make the combination made by the inventor.

Patent Law > Claims & Specifications > Enablement Requirement > General Overview

Patent Law > Nonobviousness > General Overview

[HN2] The nature of the problem which persisted in the art, and the inventor's solution, are factors to be considered in determining whether the invention would have been obvious to a person of ordinary skill in that art.

Patent Law > Claims & Specifications > Enablement Requirement > General Overview

Patent Law > Anticipation & Novelty > General Overview

[HN3] Whether the changes from the prior art are minor, the changes must be evaluated in terms of the whole invention, including whether the prior art provides any teaching or suggestion to one of ordinary skill in the art to make the changes that would produce the patentee's method and device.

Patent Law > Infringement Actions > Defenses > General Overview
[HN4] While invalidity is a question of law, the party asserting invalidity must by clear and convincing evidence establish facts supporting a conclusion of invalidity, and asserted inferences of fact must similarly be supported to meet this standard.

Patent Law > Anticipation & Novelty > General Overview
[HN5] Whether a document is a printed publication is a legal determination based on underlying fact issues.

Patent Law > Anticipation & Novelty > General Overview
[HN6] See *35 U.S.C.S. § 102.*

Patent Law > Anticipation & Novelty > General Overview
[HN7] A document, to serve as a printed publication, must be generally available.

Patent Law > Jurisdiction & Review > Standards of Review > Abuse of Discretion Review
[HN8] Abuse of discretion may obtain when the ruling reflects an erroneous application or interpretation of law, or shows a clear error of judgment, or is based on clearly erroneous factual findings.

Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview
[HN9] See *37 C.F.R. § 1.312* (1969).

Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview
[HN10] See Manual of Patent Examining Procedure § 608.01(1) (3d ed., rev. June 1968).

Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview
[HN11] See Manual of Patent Examining Procedure § 714.16.

Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview
[HN12] Although lapse on the part of an examiner does not exculpate an applicant whose acts are intentionally deceptive, any doubt as to whether the examiner lapsed in his duty does not increase the burden on the applicant. Nor does the applicant's obligation of candor replace the examiner's duty to examine the claims.

Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview
[HN13] Entry of a Rule 312 amendment requires both the recommendation of the primary examiner and approval by the Commissioner. *37 C.F.R. § 1.312.*

Governments > Federal Government > Employees & Officials
[HN14] It is presumed that public officials do their assigned jobs.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
[HN15] Gross negligence has been used as a label for various patterns of conduct. A finding that a particular conduct amounts to gross negligence does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
[HN16] Intent to deceive should be determined in light of the realities of patent practice, and not as a matter of strict liability whatever the nature of the action before the Patent and Trademark Office.

Patent Law > Inequitable Conduct > Burdens of Proof
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
[HN17] A patentee's oversights are easily magnified out of proportion by one accused of infringement. Given the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive, clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required.

Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview
[HN18] See 37 C.F.R. § 1.118(a).

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview
[HN19] The patent applicant is required to advise the patent examiner of all information known to the applicant that a reasonable examiner would consider important in deciding whether to allow the application to issue as a patent. *37 C.F.R. § 1.56(a)* (1989).

Patent Law > Claims & Specifications > Best Mode > Fact & Law Issues

Patent Law > Jurisdiction & Review > Standards of Review > General Overview
[HN20] Compliance with the best mode requirement is a question of fact, and is reviewed for clear error.

Patent Law > Claims & Specifications > Enablement Requirement > General Overview
[HN21] See *35 U.S.C.S. § 112.*

Patent Law > Claims & Specifications > Enablement Requirement > Proof
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Claims & Specifications > Description Requirement > General Overview
[HN22] Invalidity for lack of enablement is a conclusion of law and must be supported by facts proved by clear and convincing evidence, for the grant of the patent by the Patent and Trademark Office carries with it the presumption of validity including compliance with *35 U.S.C.S. § 112.*

Patent Law > Claims & Specifications > Enablement Requirement > Standards & Tests
[HN23] A decision on the issue of enablement requires determination of whether a person skilled in the pertinent art, using the knowledge available to such a person and the disclosure in the patent document, could make and use the invention without undue experimentation. It is not fatal if some experimentation is needed, for the patent document is not intended to be a production specification.

Patent Law > Claims & Specifications > Enablement Requirement > General Overview
[HN24] When the challenged subject matter is a computer program that implements a claimed device or method, enablement is determined from the viewpoint of a skilled programmer using the knowledge and skill with which such a person is charged. The amount of disclosure that will enable practice of an invention that utilizes a computer program may vary according to the nature of the invention, the role of the program in carrying it out, and the complexity of the contemplated programming, all from the viewpoint of the skilled programmer.

Patent Law > Jurisdiction & Review > Standards of Review > General Overview
[HN25] The district court's trial management should not be impeded by second guessing at the appellate level except in those rare instances when a clear abuse of discretion is firmly shown.

Patent Law > Infringement Actions > Infringing Acts > General Overview
[HN26] Infringement is not avoided if a claimed feature performs not only as shown in the patent, but also performs an additional function.

COUNSEL:

Donald R. Dunner, Finnegan, Henderson, Farabow, Garrett & Dunner, of Washington, District of Columbia, argued for Plaintiff-Appellant. With him on the brief was J. Michael Jakes. Also on the brief were George W. Whitney, Henry Y.S. Tang and Richard S. Clark, Brumbaugh, Graves, Donohue & Raymond, of New York, New York, of Counsel.

Jerry R. Selinger, Baker, Mills & Glast, of Dallas, Texas, argued, for Defendant/Cross-Appellant. With him on the brief were Andrew S. Viger and Martha E. Waters.

JUDGES:

Markey, * Newman and Archer, Circuit Judges. Newman, Circuit Judge, concurring in part, dissenting in part.

* Circuit Judge Markey vacated the position of Chief Judge on June 27, 1990.

OPINIONBY:

PER CURIAM

OPINION:

[*933] Northern Telecom, Inc., successor-in-interest to Sycor, Inc. (together herein "Sycor"), appeals the decision of the United States District Court for the Northern District of Texas. *Northern Telecom, Inc. v. Datapoint Corp.*, No. CA3-82-1039-D (N.D. Tex. Aug. 31, 1988). [**2] Datapoint Corporation has filed a cross-appeal. At issue are the validity and enforceability of United States Patent No. *3,760,375* ("the *'375* patent"), and infringement by Datapoint.

We affirm the district court's holding that certain claims had not been proved invalid under *35 U.S.C. § § 102* and 103, that certain claims are infringed, and that certain claims are invalid for failure to comply with the best mode requirement of *35 U.S.C. § 112.* We reverse the district court's holdings of invalidity for failure to comply with the enablement requirement of *35 U.S.C. § 112.* We reverse the equitable determination of unenforceability based on inequitable conduct.

The Invention

The *'375* patent, entitled "Source Data Entry Terminal", inventors Samuel N. Irwin and Michael R. Levine, relates to a mode of "batch processing" of data. In batch processing, data are entered by the operator and stored, off-line, n1 the operator not interacting with the computer but simply with the batch data entry device.

> n1 "Off-line" means not actively connected to the computer, in contrast to "on-line", wherein the terminal is connected by a communication link so that signals are transmitted directly between the terminal and the computer.

[**3]

Batch data preparation and entry were not new. Systems in common use at the time this invention was made included the IBM punch card, the paper tape punch, and the key-to-magnetic tape recorder. The invention of the *'375* patent, a programmable processor-based batch data entry terminal, provided an improved way of entering, verifying, and storing data. Entry and verification of data at the source by persons who understand the data removes a source of error in data processing. The inventors built a major business on the invention of the *'375* patent.

In accordance with the *'375* invention, the data are keyed into a form that is displayed on the screen; the operator is guided by names and instructions on the screen; and certain entries are subject to automatic as well as visual checks and edits. A storage area, or buffer, holds the data as it is entered and, when the buffer holds a complete and correct record, the data are transferred to a magnetic tape cassette.

[*934] Sycor filed suit charging Datapoint with infringement of the *'375* patent. Datapoint raised numerous defenses and counterclaims. The cause was vigorously litigated, the trial taking seventy days over a six-month [**4] period. The district court issued extensive findings of fact and conclusions of law, in a 219 page opinion. Each side appeals certain of the issues that were decided adversely to it.

I

Obviousness -- 35 U.S.C. § 103

Datapoint appeals the district court's determination that Datapoint did not prove by clear and convincing evidence facts requiring a holding that claims 35-37, 40-42, and 44 are invalid under § 103. Datapoint also raises the issue of invalidity under § 103 of claims 19, 20, and 25-28.

Datapoint relies as prior art on the Lincoln Laboratory Instrument Computer (LINC), developed in 1962 by expert witness Professor Clark, running the Patient Interview program, written by a Dr. Slack. The LINC is described as a stored program computer designed for laboratory use, consisting of a keyboard for data entry and commands to the computer, an electronics cabinet, an oscilloscope information display, and reel-to-reel digital magnetic tape units for storing data and programs.

Claims 40-42 and 44

Claim 40 is as follows:

> 40. A method of implementing a source data entry terminal device, comprising the steps:
>
> connecting selected input/output [**5] peripheral components including at least a keyboard data entry means and a visual data display means to a buffer memory and to a central processor organization, and using said buffer memory for temporary storage of data entered by said keyboard means;
>
> incorporating control logic for all such peripheral components in the central processor and controlling each such component by the central processor, such that said peripheral components need have substantially no local control logic of their own;
>
> and dedicating the terminal to a given operational configuration by incorporating a fixed program in said central processor.

Claims 41, 42, and 44 are dependent upon claim 40, and contain additional limitations.

The district court found that the final step of claim 40, requiring a fixed program, differed from the LINC because the LINC did not employ a fixed program. Datapoint contends on this appeal, as it did at trial, that this difference is a "routine design choice".

Sycor does not dispute that fixed programs are not new: inventor Irwin, in his testimony, gave the example of a calculator. Sycor describes the invention of the *'375* patent as a new combination of known steps [**6] and elements, that provides a new and commercially successful solution to the problems of batch data entry. Sycor states that this combination was not taught or suggested by the prior art, including the LINC and the LINC as modified by the Patient Interview program.

[HN1] It is insufficient that the prior art disclosed the components of the patented device, either separately or used in other combinations; there must be some teaching, suggestion, or incentive to make the combination made by the inventor. *Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985)* (insufficient to select from the prior art the separate components of the inventor's combination, using the blueprint supplied by the inventor); *Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1546, 221 USPQ 1, 7 (Fed. Cir. 1984)* ("As this court has held, 'a combination may be patentable whether it be composed of elements all new, partly new or all old'") (citations omitted); *W. L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1551, 220 USPQ 303, 312 (Fed. Cir. 1983),* [**7] *cert. denied, 469 U.S. 851, 105 S. Ct. 172, 83 L. Ed. 2d 107 (1984)* (individual references can not be "employed as a mosaic to recreate a facsimile of the claimed invention.") The district court found that the technology [*935] for the invention claimed in the *'375* patent existed at the time the invention was made, but correctly declined to engage in hindsight reconstruction of the claimed invention.

Datapoint argues that the differences between the LINC and the *'375* invention are "trivial". The district court observed that the prior art failed to teach the combination and its use as set forth in the *'375* patent, and stated that the invention's "commercial success, although not determinative of the issue, is some indication that the *'375* patent was not [sic: invention would not have been] obvious", the court referring to *Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966).*

The prior art does not suggest the Irwin/Levine solution of the *'375* invention to the batch data entry problem. As discussed in *In re Rothermel, 47 C.C.P.A. 866, 276 F.2d 393, 397, 125 USPQ 328, 332 (1960),* [**8] [HN2] the nature of the problem "which persisted in the art", and the inventor's solution, are factors to be considered in determining whether the invention would have been obvious to a person of ordinary skill in that art. *See also, e.g., Fromson v. Advance Offset Plate, Inc., 755 F.2d 1549, 1556, 225 USPQ 26, 31 (Fed. Cir. 1985)* (the prior art must suggest to one of ordinary skill in the art the desirability of the claimed combination). [HN3] Whether the changes from the prior art are "minor", as Datapoint argues, the changes must be evaluated in terms of the whole invention, including whether the prior art provides any teaching or suggestion to one of ordinary skill in the art to make the changes that would produce the patentee's method and device. *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co., 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984).*

We affirm the district court's holding that claims 40-42 and 44 had not been proved invalid on the grounds [**9] raised.

Claims 35-37

Claims 35-37 are dependent on claims 29 and 30, and include their limitations, as follows:

> 29. A method of source data capture, comprising the steps:
>
> generating coded signals representative of alpha-numeric source data desired to be captured;
>
> visually displaying the data of which said signals are representative by use of such signals;
>
> using a buffer memory to temporarily store the data being displayed;
>
> and recording the data on magnetic tape after the data has been visually displayed.
>
> 30. The method of claim 29, including the step of using a program format to generate said data-representative signals in a predetermined relative sequence, and visually displaying said data in such sequence.
>
> 35. The method of claim 30, wherein said format is used by recording it on magnetic tape and reproducing the record format prior to actual use.
>
> 36. The method of claim 35, wherein said format is recorded on magnetic tape enclosed within cassette tape cartridges, of the basic type conventionally used for audio recording.
>
> 37. The method of claim 35, wherein the format recorded on said tape is loaded into a buffer memory by replaying the tape, [**10] and the format is held in such buffer during data entry.

Datapoint asserts that claims 35-37 do not differ from the LINC with the Patient Interview program, except in trivial detail. The district court analyzed these differences. As to claim 35, the court found: "The evidence is insufficient in addressing whether the program format of the [Patient Interview] program was held in a buffer memory. The court would have to draw unwarranted inferences from the evidence to conclude otherwise."

[HN4] While invalidity is a question of law, the party asserting invalidity must by clear and convincing evidence establish facts supporting a conclusion of invalidity, and asserted inferences of fact must similarly be supported to meet this standard. Datapoint has not shown that the district court [*936] clearly erred in refusing to draw such inferences.

As to claim 36, Datapoint argues that Sycor's choice of cassette tapes to record data as opposed to the reel-to-reel system used in the LINC was "an obvious design choice." Sycor states that the use of cassette tapes in the *'375* invention was [**11] a significant aspect of the *'375* invention as a whole, and there was extensive evidence supporting its position. Datapoint does not show that the prior art suggests the Sycor combination. *Rosemount, 727 F.2d at 1546, 221 USPQ at 7.*

Datapoint has not by clear and convincing evidence established facts requiring the conclusion that the subject matter of claims 35-37 would have been obvious in terms of § 103. The holding of the district court in respect of claims 35-37 is affirmed.

Claims 19, 20, 25-28

The parties dispute whether Datapoint adequately raised the issue of the validity of claims 19, 20, and 25-28, based on the LINC as prior art. In view of our holding that these claims are invalid on other grounds, see Part V, *infra*, we do not consider this issue.

II

Anticipation -- 35 U.S.C § 102(b)

Datapoint challenges the district court's finding that claims 40-42 and 44 were not anticipated by certain "AESOP-B" documents because these documents were not "printed publications" in terms of *35 U.S.C. § 102*(b). n2 [**12] [HN5] Whether a document is a "printed publication" is "a legal determination based on underlying fact issues". *In re Hall, 781 F.2d 897, 899, 228 USPQ 453, 455 (Fed. Cir. 1986).*

> n2 ***35 U.S.C. § 102***: [HN6] A person shall be entitled to a patent unless
>
> (b) the invention was patented or described in a printed publication . . . more than one year prior to the date of the application for patent in the United States.

The AESOP-B was a complex military system for on-line distributed computer processing of logistical data such as the positions of aircraft. The documents in question are four reports on aspects of this system, identified as exhibits DX-2 through DX-5. The reports DX-2 through DX-5 were not under security classification, and were distributed to approximately fifty persons or organizations involved in the AESOP-B project. Document DX-5 contained the legend "Reproduction or [**13] further dissemination is not authorized . . . not for public release." The district court found that documents DX-2 through DX-4 "may have" contained such notices, the court finding that they "were of the class of documents that would have been distributed with such a notice." The documents were housed in a library at the Mitre Corporation, the company having principal responsibility for developing AESOP-B. Access to the library was restricted to persons authorized by Mitre.

[HN7] A document, to serve as a "printed publication", must be generally available. *Garrett Corp. v. United States, 190 Ct. Cl. 858, 422 F.2d 874, 878, 164 USPQ 521, 524 (1970)* ("While distribution to government agencies and personnel alone may not constitute publication . . . distribution to commercial companies without restriction on use clearly does.") *See Massachusetts Institute of Technology v. AB Fortia, 774 F.2d 1104, 1109, 227 USPQ 428, 432 (Fed. Cir. 1985)* (paper orally presented at a scientific meeting open to all persons interested in the subject matter, with written copies distributed [**14] without restriction to all who requested it, is a printed publication); *In re Wyer, 655 F.2d 221, 226-27, 210 USPQ 790, 795 (CCPA 1981)* (foreign patent applications that are made known to and are available to the public without restriction are publications).

The district court, referring to "the uncertainties of public access to the AESOP-B documents", found that Datapoint had failed to prove by clear and convincing evidence facts requiring a conclusion that these documents were "sufficient as prior publications, descriptive of the AESOP-B". The district court was unable to find that [*937] anyone could have had access to the documents by the exercise of reasonable diligence. *See Massachusetts Inst., supra.* We are unpersuaded that the evidence shows otherwise. Accordingly, we affirm that these documents were not printed publications.

Because the documents were not as a matter of law printed publications, we do not reach the issue of whether the AESOP-B system disclosed all the limitations of claim 29, on which claims 35-37 depend.

The district court's holding that claims 40-42 and 44 were not shown to be invalid under § 102(b) is affirmed. [**15]

III

Inequitable Conduct -- The Rule 312 Amendment

The district court held all the claims of the *'375* patent unenforceable based on inequitable conduct before the Patent and Trademark Office ("PTO"). On appellate review we apply the abuse of discretion standard. *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 876, 9 USPQ2d 1384, 1392 (Fed. Cir. 1988)* (*in banc* clarification of precedent). [HN8] Abuse of discretion may obtain when the ruling reflects an erroneous application or interpretation of law, or shows a clear error of judgment, or is based on clearly erroneous factual findings. *Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1245-46, 9 USPQ2d 1913, 1928 (Fed. Cir. 1989); Seattle Box Co. v. Industrial Crating & Packing, Inc., 756 F.2d 1574, 1581, 225 USPQ 357, 363 (Fed. Cir. 1985).*

A

The basis for the district court's ruling of inequitable conduct was the filing of an "Amendment Under Rule 312" during prosecution of the patent application that led to the *'375* patent.

During prosecution the examiner [**16] had objected to the application on various grounds, but eventually allowed the claims substantially as filed. After the PTO issued the notice of allowance, but before payment of the issue fee, Sycor requested amendment of the descriptive text of the patent application as authorized by PTO Rule 312, *37 C.F.R. § 1.312* (1969), which provided as follows:

> § 1.312. [HN9] Amendments after the notice of allowance of an application will not be permitted as a matter of right. However, such amendments may be made if filed not later than the date the issue fee is paid, on the recommendation of the primary examiner, approved by the Commissioner, without withdrawing the case from issue.

Sycor filed a four-page amendment under Rule 312, containing twenty-five specific changes to the specification. In explanation Sycor's patent attorney wrote:

> The present amendment under Rule 312 is primarily for the purpose of correcting certain typographical errors and other such discrepancies noted in the specification upon a final review of the same, immediately prior to payment of the issue fee. [**17]
>
> The errors and discrepancies sought to be corrected by this amendment were not noticed previously, and thus could not have been corrected before the present time; because the corrections merely add to the clarity and readability of the specifications [sic], entry of the amendment is believed to be in order and is solicited.

The district court held that five of the requested changes altered the scope of the original disclosure and the scope of the previously allowed claims. These five changes, as listed by the district court with the changes to the text underlined, were as follows:

> (1) a wired *or like* read-only memory;
>
> (2) read-only memory containing a hardwired *or otherwise fixed* program;
>
> (3) a hardwired *or fixed* program;
>
> (4) a wired *or like* ROM *of the form just mentioned* is unalterable;
>
> (5) the wired-in (*or otherwise fixed*) program in the ROM.

The examiner had written "Entry Recommended" in the margin of the Rule 312 amendment, alongside the first two changes listed above. On the official PTO [*938] form the box was checked "entered as directed to matters of form not affecting the scope of the invention."

The district [**18] court found that the attorney intentionally misrepresented the purpose and nature of these amendments, and that this misrepresentation was material to patentability.

B

Sycor argues that the amendments simply conformed the descriptive text of the specification to the claims, as required by the rules of PTO practice, and thus could not, as a matter of law, broaden the disclosure and the scope of the claims. Sycor states that such concordance is routine, and indeed can be compelled by the examiner. Sycor argues that neither intent to deceive nor materiality has been shown, and that the examiner correctly entered the amendments.

The original claims as filed are part of the patent specification. *35 U.S.C. § 112,* para. 2; *In re Benno, 768 F.2d 1340, 1346, 226 USPQ 683, 686-87 (Fed. Cir. 1985).* At the time the Rule 312 amendment was filed the claims had already been examined and allowed substantially as filed, and the subject matter added to the descriptive text by amendment was already in the allowed claims. The Manual of Patent Examining

Procedure [**19] ("MPEP") § 608.01(1) (3d ed., rev. June 1968) states:

> § **608.01(1)** [HN10] In establishing a disclosure, applicant may rely not only on the description and drawing as filed but also on the original claims if their content justifies it.
>
> Where subject matter not shown in the drawing or described in the description is claimed in the case as filed, and such original claim itself constitutes a clear disclosure of this subject matter, then the claim should be treated on its merits, and *requirements made to amend* the drawing and description to show this subject matter. [emphasis added]

Although Datapoint's witnesses testified that the changes enlarged the scope of the claims, the claims as originally filed and as allowed were already of the challenged scope, and were already part of the disclosure. *Benno, supra. See Environmental Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 699, 218 USPQ 865, 871 (Fed. Cir. 1983), cert. denied, 464 U.S. 1043, 79 L. Ed. 2d 173, 104 S. Ct. 709 (1984)* (the scope of the patent is determined by the claims).

The district court described the MPEP as requiring a "heightened showing" for [**20] entry of Rule 312 amendments which affect the disclosure, citing MPEP § 714.16, which states:

> § **714.16.** [HN11] As to amendments affecting the disclosure, the scope of any claim, or that add a claim, the remarks accompanying the amendment must fully and clearly state the reasons on which reliance is placed to show: (1) why the amendment is needed; (2) why the proposed amended or new claims require no additional research or examination; (3) why the claims are patentable and, (4) why they were not earlier presented.

The district court held that Sycor did not make the requisite statement of "reasons". The issue, however, is intent to deceive or mislead.

These amendments were not to the claims. The nature of these amendments was clear on their face, and the examiner was required to review them to determine whether they complied with law and practice. All the pertinent information was squarely before the examiner in a simple document. As stated in *Akzo N.V. v. United States Int'l Trade Comm'n, 808 F.2d 1471, 1482, 1 USPQ2d 1241, 1247 (Fed. Cir. 1986),* [**21] *cert. denied, 482 U.S. 909, 96 L. Ed. 2d 382, 107 S. Ct. 2490 (1987),* "the examiner was free to reach his own conclusion. . . ."

[HN12] Although lapse on the part of an examiner does not exculpate an applicant whose acts are intentionally deceptive, *KangaROOS U.S.A. v. Caldor, Inc., 778 F.2d 1571, 1576, 228 USPQ 32, 35 (Fed. Cir. 1985),* any doubt as to whether the examiner lapsed in his duty does not increase the burden on the applicant. Nor does the applicant's obligation of candor replace the examiner's duty to examine the claims. *Kingsdown, 863 F.2d at 874 n. 8, 9 USPQ2d at 1390 n. 8.*

[*939] [HN13] Entry of a Rule 312 amendment requires both the recommendation of the primary examiner and approval by the Commissioner. *37 C.F.R. § 1.312, supra.* The record shows that entry of these amendments was expressly approved. We do not think the attorney's words "typographical errors and other such discrepancies" in the introductory paragraphs of the [**22] amendment must be deemed to have diverted the examiner from mandatory review of the ensuing subject matter, in view particularly of the examiner's specific recommendation that the amendment be entered. [HN14] It is presumed that public officials do their assigned jobs. *American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359, 220 USPQ 763, 770* (Fed. Cir.), *cert. denied, 469 U.S. 821, 83 L. Ed. 2d 41, 105 S. Ct. 95 (1984).*

The subjective nature of the factual determination of intent to deceive, which is the predicate to a holding of inequitable conduct, invites litigation and indeed had led to seemingly inconsistent decisions in the Federal Circuit. The district court here did not have the benefit of our guidance in *Kingsdown*, in which we sat *in banc* for the purpose, *inter alia*, of clarifying certain of our precedents. As stated therein:

> [HN15] "Gross negligence" has been used as a label for various patterns of conduct. . . . We adopt [**23] the view that a finding that a particular conduct amounts to "gross negligence" does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must

> indicate sufficient culpability to require a finding of intent to deceive. *See Norton v. Curtiss, 57 C.C.P.A. 1384, 433 F.2d 779, 167 USPQ 532 (CCPA 1970).*

863 F.2d at 876, 9 USPQ2d at 1392.

The district court held that Sycor's misrepresentation of the nature of the amendment sufficed to support a holding of inequitable conduct before the Patent and Trademark Office. The district court described the attorney's communication as "disingenuous." The court stated that the "case law makes clear that, although a party's underlying conduct may be acceptable, that fact does not exculpate the party from an inequitable conduct finding [sic: holding] where the party misrepresented the nature of the underlying conduct to the PTO."

[HN16] Intent to deceive should be determined in light of the realities of patent [**24] practice, and not as a matter of strict liability whatever the nature of the action before the PTO. *Accord Pfizer, Inc. v. International Rectifier Corp., 538 F.2d 180, 186, 190 USPQ 273, 278 (8th Cir. 1976), cert. denied, 429 U.S. 1040, 50 L. Ed. 2d 751, 97 S. Ct. 738 (1977).* [HN17] "A patentee's oversights are easily magnified out of proportion by one accused of infringement. . . ." *Id. at 196, 190 USPQ at 286.* Given the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive, clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required.

When all of the circumstances are considered, including indications of good faith, we are left with a definite and firm conviction that a mistake has been made regarding Sycor's state of mind when it filed its Rule 312 amendment in the Patent and Trademark Office. *Anderson v. City of Bessemer City, N.C., 470 U.S. 564, 84 L. Ed. 2d 518, 105 S. Ct. 1504 (1985); Kingsdown, 863 F.2d at 876, 9 USPQ2d at 1392;* [**25] *FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1416, 5 USPQ2d 1112, 1116 (Fed. Cir. 1987)* (intent must be determined in view of all the circumstances). Here, there was no failure of compliance with 37 C.F.R. § 1.118(a), which states that:

> § **1.118(a)** [HN18] All amendments to the specification, including the claims, and the drawings filed after the filing date of the application must conform to at least one of them as it was at the time of the filing of the application.

Even if Sycor's statement in its covering letter to the examiner was in error or negligent, the Rule 312 amendment was made as of right, authorized by MPEP § 608.01(1). This right weighs against an inference of intent to deceive the examiner into entering the amendment.

[*940] Accordingly, we conclude that the district court's finding that Sycor intended to mislead or deceive the Patent and Trademark Office is clearly erroneous. Thus we need not reach the question of materiality, for absent the element of intent the court's holding of inequitable conduct was legal error, and thus exceeded [**26] the court's discretionary authority. The holding of unenforceability on this ground is reversed.

IV

Inequitable Conduct -- The Viatron 21 Device

Datapoint appeals the district court's ruling that Sycor did not commit inequitable conduct by not disclosing the Viatron 21 device to the patent examiner.

[HN19] The patent applicant is required to advise the patent examiner of all information known to the applicant that "a reasonable examiner would consider important in deciding whether to allow the application to issue as a patent". *37 C.F.R. § 1.56(a)* (1989). This requirement has grown in importance because of the highly technical nature of the subject matter of many patent applications, the difficulties inherent in searching the worldwide technical literature, and the unique knowledge that the applicant may hold.

According to Datapoint, the existence of the Viatron 21 device became known to inventor Irwin during the time that Irwin was working on the invention of the *'375* patent, including knowledge that the Viatron 21 used a tape cassette, albeit in a different system for data processing. [**27]

The district court found that the Viatron 21 device was not available as prior art. Datapoint does not on appeal challenge that finding, but merely calls the Viatron 21 "prior art" in arguing that it should have been disclosed. Since the Viatron 21 device was not prior art, it was not material to patentability. *Environmental Designs, 713 F.2d at 698, 218 USPQ at 870.* Absent materiality, inequitable conduct for failure to disclose can not lie.

The district court's determination on this point is affirmed.

V

Best Mode -- 35 U.S.C. § 112

The district court held that claims 19-20, 22, and 24-28 of the *'375* patent are invalid on the basis that Sycor concealed the best mode of carrying out the invention of these claims. [HN20] Compliance with the best mode requirement is a question of fact, and is reviewed for clear error. *DeGeorge v. Bernier, 768 F.2d 1318, 1324, 226 USPQ 758, 763 (Fed. Cir. 1985).*

One of the objectives of the disclosed invention was to capture data "on magnetic tape cassettes of the general type presently [**28] finding extensive and widespread usage in audio entertainment equipment, but never heretofore used in data-handling apparatus." (Col. 1, lines 59-63.) The specification also stated that the invention includes cassettes "of the type which are almost universally available for audio purposes." (Col. 3, lines 32-33.) The district court, however, found that Sycor knew, in advance of filing the patent application, that standard audio tape was not the best mode for carrying out the invention. This finding is amply supported by the testimony of a former Sycor Vice-President-Engineering who was an employee of Sycor at the time the patent application was filed, and by other evidence, that Sycor purchased tape and cassettes of its own design and specifications and that these were different from standard audio tapes in their yield strength and magnetic characteristics.

Sycor argues that, at the time of the patent application, the 3M commercial audio tape that was on the market met its specifications. If so, it is this tape (or Sycor's own specifications) that had to be disclosed to satisfy the best mode requirement of *35 U.S.C. § 112,* para. 1. While Sycor's argument may [**29] be relevant to enablement, it does not establish the best mode "contemplated by the inventor," which is a subjective inquiry. *See Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 3 USPQ2d 1737 (Fed. Cir. 1987); see also Dana Corp. v. IPC Ltd. Partnership,* [*941] *860 F.2d 415, 8 USPQ2d 1692 (Fed. Cir. 1988).*

The district court's determination on this point is affirmed.

VI

Enablement -- 35 U.S.C. § 112

Claims 1, 3, 5-7, 9-12, 14-20, 22, 29-33, 35-42, and 44 were held invalid for lack of enablement. The district court held that the patent specification did not contain an enabling disclosure of the software program used to carry out the claimed invention, stating that "the patent specification's lack of any information concerning the invention's programs would require a person reasonably skilled in the art of computer programming to experiment unduly in attempting to write programs for the *'375* device."

[HN21] *35 U.S.C. § 112* para. 1 provides that:

> The specification shall contain a written [**30] description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

[HN22] Invalidity for lack of enablement is a conclusion of law and must be supported by facts proved by clear and convincing evidence, for the grant of the patent by the PTO carries with it the presumption of validity including compliance with § 112.

[HN23] A decision on the issue of enablement requires determination of whether a person skilled in the pertinent art, using the knowledge available to such a person and the disclosure in the patent document, could make and use the invention without undue experimentation. It is not fatal if some experimentation is needed, for the patent document is not intended to be a production specification. *In re Gay, 309 F.2d 769 at 774, 135 USPQ at 316. See Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984)* [**31] (discussing the amount of experimentation).

[HN24] When the challenged subject matter is a computer program that implements a claimed device or method, enablement is determined from the viewpoint of a skilled programmer using the knowledge and skill with which such a person is charged. The amount of disclosure that will enable practice of an invention that utilizes a computer program may vary according to the nature of the invention, the role of the program in carrying it out, and the complexity of the contemplated programming, all from the viewpoint of the skilled programmer. *See In re Sherwood, 613 F.2d 809, 817, 204 USPQ 537, 544 (CCPA 1980), cert. denied, 450 U.S. 994, 68 L. Ed. 2d 193, 101 S. Ct. 1694 (1981).* As the court observed in *Sherwood*, the writing of a program may require varying degrees of skill:

> In general, writing a computer program may be a task requiring the most sublime of the inventive faculty or it may require only the droning use of clerical skill. The difference between the two extremes lies in the creation of mathematical methodology [**32] to bridge the gap between the information one starts with ("the input") and the information that is desired ("the output").

613 F.2d at 816-17, 204 USPQ at 544.

The claimed invention of the *'375* patent is not in the details of the program writing, but in the apparatus and method whose patentability is based on the claimed combination of components or steps. Further, experts for both sides testified that an experienced programmer could, without unreasonable effort, write a program to carry out the invention of the *'375* patent. The possible design of superior software, or whether each programmer would work out the details in the identical way, is not relevant in determining whether the inventor has complied with the enablement requirement.

Expert witnesses testifying for Datapoint agreed that there were various ways of writing a program that would perform the *'375* invention. Gordon Bell, Earle Pughe, and Fernando Corbato all testified that it would be relatively straightforward for a skilled computer programmer to design [*942] a program to carry out the claimed invention.

In Bell's deposition testimony, contrary to his testimony at trial, he averred: [**33]

> Q. Would it have been obvious in June of '69 for someone of ordinary skill to write the program for a computer to operate as a source data entry terminal given the functions of the source data entry terminal?
> A. Yes.

Earle Pughe testified:

> Q. And could anybody have built -- reasonably skilled in the art built a fixed-program read-only memory device with a source data entry program?
> A. Yes, sir.

Fernando Corbato, another Datapoint expert, testified:

> There is a tremendous amount of lore and understanding that one must have in order to carry it out which depending on who you are dealing with may or may not be state of the art. To someone with a, a skilled computer designer, it would appear to be very, very straightforward to do anything that was described in the patent. He probably would have felt that he had already been doing that. The problem was I don't think the patent describes any novel configuration.

The district court referred in its opinion to the testimony of Kay Magleby that one skilled in the art of computer programming would be hindered because such a person could not tell where the program format would [**34] be loaded, what would be a typical program format, what characters would be used, or what would be the range or limitations of the format program. Sycor points out that the *'375* patent specification states that the format program is stored in the delay line buffer memory. On cross-examination, Magleby acknowledged that the specification contains a description of how the format program is entered into the delay line buffer memory:

> So here [in the *'375* patent] I see a description of how, whatever this format program is, is entered into the delay line and stored on cassette tape.

In another exchange with Magleby:

> Q. Would one of ordinary skill have any difficulty in determining what the instruction format would be?
> A. I think one of ordinary skill could develop a product that would satisfy the claims of the patent.
>
> However, if there's something unique about this particular product as represented in the claims, then I think it should be explained clearly enough in the specification so that we can understand what's unique.

The format program is described in the specification as "character codes which are representative of and which initiate [**35] machine control functions." Datapoint's witness Professor Clark testified that additional information such as detailed flow charts, block diagrams, or source code listings were necessary in order to avoid spending experimental time. However, as noted in *Sherwood*, a description of such information may be adequate to a skilled programmer:

> In assessing any computer-related invention, it must be remembered that the programming is done in a computer language. The computer language is not a conjuration of some black art, it is simply

> a highly structured language. . . . The conversion of a complete thought (as expressed in English and mathematics, i.e. the known input, the desired output, the mathematical expressions needed and the methods of using those expressions) into a language a machine understands is necessarily a mere clerical function to a skilled programmer.

613 F.2d at 817 n. 6, 204 USPQ at 544 n. 6. Although there have been circumstances wherein production of the computer program was not routine, as in *White Consol. Indus., Inc. v. Vega Servo-Control, Inc., 713 F.2d 788, 791, 218 USPQ 961, 963 (Fed. Cir. 1983),* where the production [**36] of the program required one and one half to two person-years of work, such circumstances were not shown or suggested for the *'375* invention.

[*943] The great weight of the expert testimony on both sides was that a programmer of reasonable skill could write a satisfactory program with ordinary effort. This requires the conclusion that the programs here involved were, to a skilled programmer, routine. The district court's finding that undue experimentation was necessary to write the program is clear error.

The holding that the claims are invalid for lack of enablement is reversed.

VII

Infringement -- 35 U.S.C. § 271

Datapoint challenges the district court's finding that claims 19, 20, 25-28, 35-37, 40-42, and 44 of the *'375* patent are infringed.

The Excluded Evidence

Datapoint argues that the district court erred in finding infringement of claims 40-42 and 44, in that the court unfairly barred Datapoint from introducing evidence to rebut the testimony of Sycor's witness Dr. Larky with respect to the term "fixed program".

Datapoint states that the definition of "fixed program" was presented in the *'375* patent and in pre-trial discovery [**37] as a program that was "not easily changeable" by the data entry operator, and that Larky changed the definition during his testimony to a program that was "not self-modifying and which the operator could not alter." Datapoint states that the latter definition is correct, but that this was a substantial change, and a surprise at trial. To support its position of non-infringement based on this definition, Datapoint sought to introduce, at trial, excerpts from its source codes. Datapoint states that the surprise definition of a fixed program made the source codes relevant.

Sycor objected to this proffered evidence, on the ground that the source codes were requested during discovery, were refused by Datapoint and, despite an order to compel production, were never produced. Sycor states that Datapoint did not object to Larky's testimony as surprise when it was given, or for four months thereafter, or offer during that period to produce this previously-withheld information. Indeed, the source codes were offered into evidence on the last day of Datapoint's testimony in chief.

On this history, we conclude that the district court did not abuse its discretion in refusing to receive this [**38] evidence. *United States v. Cohen, 888 F.2d 770, 774 (11th Cir. 1989)* ("Absent an abuse of discretion, evidentiary rulings of the trial court will stand.") [HN25] The court's trial management "should not be impeded by second guessing at the appellate level except in those rare instances when a clear abuse of discretion is firmly shown." *Rosemount, 727 F.2d at 1549-50, 221 USPQ at 10* (upholding exclusion of expert testimony where expert not identified before trial despite court order).

We have carefully considered Datapoint's arguments and authorities, but Datapoint has not shown that the circumstances of this case show prejudicial error, or exceeded the trial court's discretionary authority. The exclusion of the source codes is not grounds for reversal or other remedial action.

The Burden of Proof

Datapoint argues that the district court shifted to Datapoint the burden of proving non-infringement, rather than requiring Sycor to meet its burden of proving infringement by a preponderance of evidence. Datapoint contends that it adequately showed at trial [**39] that the accused programs were self-modifying (i.e., not "fixed") in that they used "overstoring," and thus that Sycor had not met its burden of proof.

Sycor had provided evidence, through the testimony of its expert witnesses, that each element or step of the claims was embodied in Datapoint's equipment and method. The court thus directed its attention to Datapoint's defenses, stating in its opinion:

> The court recognizes that Sycor has the burden of proving by a preponderance of the evidence that Datapoint has infringed the *'375* patent by Datapoint's hardware-software equipment combinations. [*944] Nevertheless, Datapoint has purported seriously to challenge Sycor's expert testimony in six areas. The court has therefore determined

> to approach the infringement issues, not from the standpoint of Sycor's affirmative assertions, but from Datapoint's defensive assertions. Except to the extent the court finds non-infringement in its findings below, the court is satisfied that, were the patent valid and enforceable, Sycor's evidence is otherwise sufficient to prove infringement by a preponderance of the evidence.

This statement does not support Datapoint's position [**40] that the district court required Datapoint to prove non-infringement by a preponderance of evidence.

In its defense Datapoint had presented evidence that there are three types of overstoring: overlays, the DOS interrupt handler, and the NOP JUMP instruction. The district court's opinion discusses the technological details, which need not be repeated here. The district court found that although the accused Datapoint devices had the capability of overstoring, Datapoint did not show that this capability was used. The court found that Datapoint had not shown that such overlays must occur in the DOS, and the court found that any possible use of overlays was not adequately explained. The court also found that Datapoint's DATASHARE interpreters use overlays, but that the evidence presented did not show sufficiently clearly that the overlays must be used. The court further found that the NOP JUMP instruction could not be used in most of the accused programs. While Datapoint contends that these findings show that the burden of proof was shifted to it, Datapoint has not shown that the trial court wavered from correct application of the burdens.

The court found in favor of Datapoint that [**41] the DATABUS 15 interpreter 32K memory device was not a fixed program, and did not infringe. Sycor does not challenge this holding. However, Datapoint makes the argument that none of its products infringe because "Datapoint users have the option to program any Datapoint DATASHARE or DATABUS system for at least part of its hardware configuration". Datapoint refers to certain pages in its user manuals, one of which describes a "default configurator" that permits the user "to configure the run-time characteristics of his DATABUS interpreter," and another of which states that it "supports many configurations . . . via configuration options".

Sycor responds that the term "operational configuration" of claim 40, understood in light of the *'375* patent specification, means at least the peripheral configuration of the terminal, such as input, output, and recording devices. Sycor explains that the fixed program of the *'375* patent provides control for a given combination of specific peripherals, i.e., the hardware configuration, and contains the definitions of various keys, defined through the execution of the ROM program to initiate the action of the peripheral devices.

These arguments [**42] were generally before the district court. Datapoint has not met its burden of showing that the district court clearly erred in its findings. The information in Datapoint's user manuals on possible hardware or peripheral configuration at the user's option may, as Datapoint states, show that additional functions may be performed, but does not show clear error in the district court's holding that infringement of these claims was established by a preponderance of the evidence.

Claims 35-37

While the parties dispute whether Datapoint used the phrase "reverse doctrine of equivalents" at trial, we agree with Datapoint that the substance of the argument was raised. Datapoint argued that even if these claims appear to read literally on the Datapoint equipment, the products are changed in such substantial ways from that described in the *'375* patent that infringement can not be found. *See SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1123, 227 USPQ 577, 587 (Fed. Cir. 1985) (in banc)* (discussing the reverse doctrine of equivalents).

[*945] Datapoint states that its accused products are general purpose computers, rather than a special purpose [**43] terminal using a replaceable, hard-wired ROM, as contemplated in the *'375* patent. Datapoint argues, as it did at trial, that its products are capable of processing data as the data are entered, and therefore that its products are not source data entry terminals. Datapoint states that its devices are so changed that, despite a literal reading of the claims on these devices, infringement is avoided under the "reverse doctrine". The district court agreed that Datapoint's products have some features in common with general purpose computers, but held that these features did not defeat infringement.

The addition of features does not avoid infringement, if all the elements of the patent claims have been adopted. *Radio Steel & Mfg. Co. v. MTD Prods., 731 F.2d 840, 848, 221 USPQ 657, 663-64* (Fed. Cir.), *cert. denied, 469 U.S. 831, 83 L. Ed. 2d 62, 105 S. Ct. 119 (1984).* Nor is [HN26] infringement avoided if a claimed feature performs not only as shown in the patent, but also performs an additional function. *Id. at 848, 221 USPQ at 664.* We have carefully [**44] considered Datapoint's argument that its hardware is "quite different" from that described in the *'375* patent. We conclude that Datapoint has not shown clear error in the district court's finding of infringement by a preponderance of evidence.

Datapoint blames the success of Sycor's position as to infringement on the subject matter entered into the descriptive portion of the specification by the challenged Rule 312 amendment, see Part III *ante*. Sycor asserts that the district court did not adopt whatever enlarged claim interpretation Datapoint states Sycor intended to obtain through the Rule 312 amendment. Datapoint directs us to no apparent reliance by the district court on the descriptive text as modified under Rule 312.

Datapoint has shown no clear error in the district court's findings of infringement. The holding of infringement is affirmed.

VIII

Laches

Datapoint asserts that the district court erred in not finding material prejudice due to Sycor's asserted period of inaction in enforcing the *'375* patent. The district court did not decide the question of laches, stating: "That the court has found for Datapoint today precludes a finding of material prejudice. [**45] " Because we have reversed the majority of the rulings in favor of Datapoint, the defense of laches may require resolution. The issue is pertinent to the assessment of damages because it may affect the period of recovery for infringement. *See Sun Studs, Inc. v. ATA Equip. Leasing, Inc., 872 F.2d 978, 1989 U.S. App. LEXIS 9608, 11 USPQ 2d 1479, 1479 (Fed. Cir. 1989)* (remanding for determination of laches).

The merits of the issue were not argued on this appeal, both sides agreeing that remand to the district court would be appropriate. Thus during the damages phase the court may consider the question of laches if it is duly raised.

IX

Other Issues

We have considered all the additional issues and arguments raised in the appeal and the cross-appeal. None changes the views expressed and decisions reached herein.

Costs

Taxable costs shall be assessed in favor of Northern Telecom.

Summary

Claims 19-20, 22 and 24-28 are invalid for failure to disclose the best mode. Claims 35-37, 40-42, and 44 are not invalid, are enforceable, and are infringed.

The cause is remanded for further proceedings consistent herewith.

AFFIRMED IN PART, REVERSED IN [**46] PART AND REMANDED.

CONCURBY:

NEWMAN (In Part)

DISSENTBY:

NEWMAN (In Part)

DISSENT:

[*946] NEWMAN, Circuit Judge, concurring in part, dissenting in part.

I share the court's opinion as to Parts I through IV, and VI through IX. I respectfully dissent from the holding in Part V that certain claims are invalid for failure to comply with the "best mode" requirement of *35 U.S.C. § 112.*

A holding of invalidity on this ground requires that the inventor knew of and concealed a better mode than was disclosed in the patent application. *Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384-85, 231 USPQ 81, 94 (Fed. Cir. 1986).* It is facile, and erroneous, to infer that information not included in a patent application was necessarily concealed. Patent applications rarely contain every detail, for that is not their function, but infringers constantly seek to enlarge any omission into a fatal flaw. Challenge is easy; the penalty is extreme. Thus precedent requires that violation of the "best mode" provision be established by clear and convincing evidence. *Hybritech, 802 F.2d at 1384, 231 USPQ at 94.*

The fatal flaw with [**47] which Sycor was charged was the statement in the patent specification that standard audio tape cassettes were used to record the data, the district court holding that Sycor knew that standard audio tape was not the best mode. At the trial witnesses testified that commercial audio tape was used to record the data, that these tapes varied in quality, and that not all worked equally well. There was in evidence a document showing Sycor's specification of commercial tape parameters, including tests of tapes made by K/Tronics, TDK, 3M (Scotch brand), and ongoing tests of BASF tapes. The district court referred to Datapoint's contention that "Sycor knew at the time of filing the *'375* patent application that this cassette specification was needed to practice the best mode", and held that "Sycor did not disclose the best mode". With respect to the 3M tape referred to by the panel majority, Sycor stated that the 3M tape met all of the parameters set out in its tape specification; while Datapoint argued that the 3M tape

"apparently failed". The district court did not identify the 3M tape, or any other, as the best mode.

On this record, there was not clear and convincing evidence of concealment [**48] of a better mode known to the inventor. Nor was there any finding of concealment. It was undisputed that the specification of commercial audio tape parameters was prepared by Sycor for distribution. Distribution is inimical to concealment.

To determine whether an asserted omission amounts to concealment, such omission should be considered in light of all the circumstances. For example, consideration should be given to whether the omitted information was publicly known or readily ascertainable; whether there was any benefit to the patentee of concealment -- or the absence of benefit; the materiality of the information; whether the interested public was actually prejudiced; and any evidence tending to show good or bad faith. In this case, each of these factors weighs on the side of Sycor.

It was undisputed that persons of ordinary skill were aware of differences among commercial audio tapes. As was stated in *In re Karnofsky, 55 C.C.P.A. 940, 390 F.2d 994, 997, 156 USPQ 682, 685 (1968):*

> Where one of ordinary skill in the art would know how to select operating conditions so as to achieve a particular result, the failure to include a recitation of some specific [**49] operating conditions in the specification cannot give rise to a rejection either under the "enabling" or under the "best mode" requirement of *35 U.S.C. § 112.*

A patent document is not a "production specification". *In re Gay, 50 C.C.P.A. 725, 309 F.2d 769, 772, 135 USPQ 311, 315 (1962); Manual of Patent Examining Procedure* § 608.01(h) (8th ed. May 1988). It seems to me that the information on commercial audio tape parameters is not untypical of work that is done after an invention has been made, when development continues and data accumulate, often concurrently with patent application work. When the patent specification is fully enabling, the failure to include information that is not necessary either to describe or to enable [*947] the claimed invention should not invalidate the claims under the "best mode" provision, unless the information was withheld for the purpose of concealment of a better mode.

I would reverse the trial court's holding as based on incorrect law, and the absence of clear and convincing evidence of failure to meet the "best mode" requirement.

LEXSEE 796 F2D 443

BAUSCH & LOMB, INC., Appellant, v. BARNES-HIND/HYDROCURVE, INC., and BARNES-HIND INTERNATIONAL, INC., Appellees

No. 85-2578

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

796 F.2d 443; 1986 U.S. App. LEXIS 20297; 230 U.S.P.Q. (BNA) 416

July 14, 1986

PRIOR HISTORY: [**1]

Appealed from: U.S. District Court for the Northern District of California,

Judge Aguilar.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant sought review of a judgment of the United States District Court for the Northern District of California, which found appellant's patent invalid and issued judgment for appellee in appellant's suit for patent infringement.

OVERVIEW: Appellant instituted suit against appellee for infringement of its patent. Appellee counterclaimed that the patent was invalid. The court reversed the order because the trial court failed to give appellant's patent the presumption of validity mandated by *35 U.S.C.S. § 282.* The trial court failed to undertake Graham test factual findings required in determining the obviousness of a patent, and improperly determined that appellant's patent was obvious. The trial court relied too heavily on the alleged opinion of an inventor and patentee, and substituted that opinion for the proper standard, namely the level of skill of a hypothetical ordinary skilled person and what that person was capable of with prior art. The trial court considered evidence that was not prior art and improperly constructed appellant's claim in its infringement action. The trial court's method of assessing smoothness in appellant's claim by resort to a microscope exceeded the level of smoothness required in claims.

OUTCOME: The court vacated the lower court's decision, finding that the decision that appellant's patent was invalid was erroneous, because the lower court failed to undertake the proper factual analysis for obviousness. The lower court erroneously constructed appellant's claims in the infringement action. The court remanded the matter for proper analysis.

LexisNexis(R) Headnotes

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption
Patent Law > Infringement Actions > Burdens of Proof
[HN1] A patent shall be presumed valid, and each claim shall be presumed valid independently of the validity of other claims. The burden is on the party asserting invalidity to prove it with facts supported by clear and convincing evidence.

Patent Law > Nonobviousness > Elements & Tests > Ordinary Skill Standard
Patent Law > Ownership > Conveyances > Assignments
Patent Law > Inequitable Conduct > General Overview
[HN2] A determination of nonobviousness is based, inter alia, on the opinion of a hypothetical person of ordinary skill in the art, not on the inventors' opinion. Instances of inventors refusing even to cooperate in obtaining issuance of a patent to be owned by an assignee are common and machinery is provided in *37 C.F.R. § 1.47* to deal with them. *37 C.F.R. § 1.47* provides that either a joint inventor or a proper assignee may file the application without the consent or signature of the inventor, just so the oath or declaration is accompanied

by a petition including proof of pertinent facts. It is clear, therefore, that the United States Patent and Trademark Office does not allow the inventor to erect that type of obstacle to obtaining patent protection. Such forethought is necessary, as otherwise an inventor's changed self interest might nullify a proper assignment.

Patent Law > Infringement Actions > Burdens of Proof
[HN3] When the prior art before the court is the same as that before the United States Patent and Trademark Office (PTO), the burden on the party asserting invalidity is more difficult to meet.

Patent Law > Nonobviousness > Elements & Tests > General Overview
[HN4] Obviousness under *35 U.S.C.S. § 103* is a question of law based on the underlying factual inquiries set forth as follows and known as the Graham test: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art; and (4) objective evidence of secondary considerations.

Patent Law > Nonobviousness > Elements & Tests > Hindsight
[HN5] In patent cases, the need for express Graham findings takes on an especially significant role because of an occasional tendency of district courts to depart from the Graham test, and from the statutory standard of obviousness that it helps determine, to the tempting but forbidden zone of hindsight. Thus an appellate must be convinced from the opinion that the district court actually applied Graham and must be presented with enough express and necessarily implied findings to know the basis of the trial court's opinion.

Patent Law > Nonobviousness > Elements & Tests > Ordinary Skill Standard
Patent Law > Nonobviousness > Elements & Tests > Prior Art
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
[HN6] The issue of obviousness is determined entirely with reference to a hypothetical person having ordinary skill in the art. It is only that hypothetical person who is presumed to be aware of all the pertinent art. The actual inventor's skill is irrelevant to this inquiry, and this is for a very important reason. The statutory emphasis is on a person of ordinary skill. Inventors, as a class, according to the concepts underlying the Constitution and the statutes that have created the patent system, possess something -- call it what you will -- which sets them apart from the workers of ordinary skill, and one should not go about determining obviousness under *35 U.S.C.S. § 103* by inquiring into what patentees (i.e., inventors) would have known or would likely have done, faced with the revelation of references.

Patent Law > Nonobviousness > Elements & Tests > General Overview
[HN7] It is impermissible within the framework of *35 U.S.C.S. § 103* to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Date of Invention & Priority > General Overview
Patent Law > Nonobviousness > Elements & Tests > General Overview
[HN8] To determine whether a reference is within the scope and content of the prior art, first determine if the reference is within the field of the inventor's endeavor. If it is not, then next consider whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. Cases have focused on the claims in suit, the art the United States Patent and Trade Office applied to the claims, and the nature of the problem confronting the inventor. Further, the art must have existed as of the date of invention, presumed to be the filing date of the application until an earlier date is proved.

Patent Law > Claims & Specifications > Claim Language > Elements & Limitations
Patent Law > Nonobviousness > Elements & Tests > General Overview
[HN9] A court must view the claimed invention as a whole.

Patent Law > Claims & Specifications > Enablement Requirement > General Overview
Patent Law > Nonobviousness > Elements & Tests > General Overview
[HN10] Six factors relevant to a determination of the level of ordinary skill: educational level of the inventor, type of problems encountered in the art, prior art solutions, rapidity of innovation, sophistication of technology, and educational level of active workers in the field. As to educational level of the inventor, although the educational level of the inventor may be a factor in determining the level of ordinary skill in the art, it is by no means conclusive.

Patent Law > Nonobviousness > Elements & Tests > General Overview

[HN11] Secondary considerations, when present, must always be considered in an obviousness determination. Such evidence includes commercial success, long felt but unresolved needs, and failed attempts.

Patent Law > Infringement Actions > Infringing Acts > General Overview
Patent Law > Infringement Actions > Claim Interpretation > General Overview
[HN12] The first step in determining patent infringement is claim construction.

COUNSEL:

Laurence H. Pretty, Pretty, Schroeder, Brueggemann & Clark, of Los Angeles, California, argued for Appellant. With him on the brief was Craig S. Summers. Bernard D. Bogdin and Howard S. Robbins, Bausch & Lomb, Inc., of Rochester, New York, were also on the brief.

John M. Calimafde, Hopgood, Calimafde, Kalil, Blaustein & Judlowe, of New York, New York, argued for Appellees. With him on the brief were Eugene J. Kalil and Dennis J. Mondolino. Gilbert W. Rudman, Revlon Incorporated, of Tuckahoe, New York, of Counsel.

JUDGES:

Markey, Chief Judge, Friedman, Circuit Judge, Nichols, Senior Circuit Judge.

OPINIONBY:

NICHOLS

OPINION:

[*444] NICHOLS, Senior Circuit Judge.

Appellant Bausch & Lomb, Inc. filed suit in the United States District Court for the Northern District of California, alleging that appellee Barnes-Hind/Hydrocurve, Inc. and Barnes-Hind International, Inc. (hereinafter Barnes-Hind) infringed patent No. 4,194,814 ('814 patent) in the manufacture and sale of its laser-marked contact lens. Barnes-Hind denied infringement and counterclaimed that the '814 patent was invalid, [**2] void, and unenforceable. In No. C-83-20283-RPA, Judge Aquilar found the patent invalid for obviousness and not infringed. We vacate and remand.

[*445] Appellee Barnes-Hind relied to a large extent on deposition testimony which was never introduced into evidence. Because this testimony was not in evidence, it would have been improper for us to consider it and, therefore, we did not. This eliminated much of Barnes-Hind's arguments on appeal.

Background

1. *The Technology*

Vision correcting contact lenses have become familiar; hard contact lenses were introduced in the early 1950's and soft lenses in 1971. Toric contact lenses, which correct for the eye condition known as astigmatism, have a similar history of usage: hard lenses from the early 1950's and soft from the first half of the 1970's. Toric lenses differ from standard contact lenses in having a prism base, *i.e.*, one edge portion of the lens is thicker. Proper prescription and fitting of toric lenses on the cornea of the eye requires alignment of a central lens axis with this prism base. Markings on the contact lens surface greatly facilitate the fitting process.

Inks and other substances have [**3] been used since the early 1950's, however, those marking procedures suffer several disadvantages: difficulty of accurate application with possible FDA disapproval; possibility of dissolution, blurring, and allergic reactions. Mechanical marking, as with a sharp scribing tool or an abrading tool such as a dental bur, is also available, but not without its problems: inaccurate and inconsistent positioning of the mark, lens damage, inadequate visibility, and the expense and time involved.

2. *The Patent*

The '814 patent, entitled Transparent Opthalmic Lens having Engraved Surface Indicia, discloses an engraved contact lens and provides a method of engraving using a source of high intensity electro-magnetic energy, such as a laser. The mark, not as deep as the lens is thick, is surrounded by a smooth surface of unsublimated or unaffected polymer material with the result that edges of the markings do not inflame or irritate the eyelid of the lens wearer.

The claims in suit are 1, 2, and 7. Claim 1 provides:

> An ophthalmic lens adapted to be placed in direct contact with eye tissue formed of a transparent cross-linked polymer material, said lens being characterized by identifying [**4] indicia engraved in a surface thereof by subjecting said lens to a beam of radiation emerging from a laser having an intensity and wavelength at least sufficient to sublimate said polymer and form depressions in said lens surface to a depth less than the thickness of said lens, said lens having a smooth surface of unsublimated polymer material surrounding said depressions, and by

> varying in a predetermined manner the point at which said laser beam impinges upon said lens surfaces to engrave said identifying indicia in said lens surface.

Claim 2 depends from claim 1 with the limitation that the lens is formed by a cross-linked hydrophilic (water loving) polymer. Claim 7, a product claim, is similar to claim 1 but defines the depressions as relieved zones.

3. *The Dispute*

In February 1976, Mr. Donald Hager, then production manager at the Milton Roy Company, a manufacturer of soft contact lenses which was purchased by appellant Bausch & Lomb in 1979, sent to Carco, Inc., a distributor of laser equipment, six soft contact lenses for laser marking. At least two lenses were successfully marked. Around September 1976, Dr. David Fisher and Mr. James A. McCandless, also [**5] of Milton Roy Company, met with Mr. Hager to debrief him on the work. Soon thereafter, Mr. Hager resigned.

Dr. Fisher and Mr. McCandless continued to work on the lens-marking system, and in November 1977 filed an application for the patent in suit, listing themselves and Mr. Hager as inventors. Mr. Hager declined to execute the patent application, being at that time the employee of another lens manufacturing company, Sauflon [*446] International, Inc. and saying that he had not "invented anything in connection with laser marking of contact lens." He further said that he could not execute documents, under oath or otherwise, that represent the contrary. The Patent and Trademark Office (PTO) initially, and on a second occasion, rejected all the claims as obvious over two prior art U.S. patents to Brucker (No. 3,833,786) (teaching the use of a laser to fenestrate, *i.e.*, make holes, in contact lens to allow circulation of fluid through the lens) and to Caddell (No. 3,549,733) (disclosing the use of a laser to remove plastic from the surface of a printing plate to form a pattern). The PTO later issued the patent in 1980 as limited to a transparent cross-linked polymer having [**6] a smooth surface around the mark. Mr. Hager did sign as inventor in 1982. Meanwhile, Milton Roy commenced manufacture and marketing of laser-marked soft contact lenses in 1978.

Barnes-Hind's predecessor, Continuous Curve, Inc., introduced under the trademark HYDROCURVE a line of soft toric lenses around 1975-76 that were marked with an indentation by a bur. In 1981, Barnes-Hind offered a soft toric lens marked by a laser.

Bausch & Lomb filed suit, contending that certain laser-marked contact lenses manufactured and sold by Barnes-Hind infringe claims 1, 2, and 7 of the '814 patent. Barnes-Hind denied infringement and counterclaimed that the patent was invalid, void, and unenforceable. The parties narrowed the issue of infringement to whether the marks on the HYDROCURVE lenses are surrounded by a smooth surface of unsublimated polymer material with respect to claims 1 and 2 or a smooth and unaffected surface for claim 7.

4. *The District Court Proceedings*

The district court determined that Barnes-Hind "proved by clear and convincing evidence that the patent in suit (4,194,814) and each of its claims is invalid and therefore void." It concluded that the differences between [**7] the claims and the prior art would have been obvious, finding that "the fact that the claimed subject matter of the patent in suit was obvious to Mr. Hager is most indicative of the obviousness of the invention," and that "Dr. Brucker's experiments in laser marking contact lenses are further evidence in support of this court's finding of obviousness." The court further concluded that scanning electron microscope (SEM) photographs, showing "that the surface of these lenses surrounding the laser mark are not 'smooth and unsublimated' or 'unaffected' as those terms were defined by plaintiff [appellant] during the processing of the patent in suit," demonstrated lack of infringement in any case. Bausch & Lomb appealed.

Opinion

The judgment is premised on several legal errors: (1) disregard of the presumption of validity established by *35 U.S.C. § 282;* (2) absence of the factual findings on the four inquiries mandated by *Graham v. John Deere Co., 383 U.S. 1, 17, 148 U.S.P.Q. (BNA) 459, 467, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966);* and (3) improper claim construction leading to the conclusion of noninfringement. We vacate the court's opinion [**8] and remand for a determination consistent with this opinion.

1. *Presumption of Validity*

[HN1] A patent shall be presumed valid, and each claim shall be presumed valid independently of the validity of other claims. *35 U.S.C. § 282.* The burden is on the party asserting invalidity to prove it with facts supported by clear and convincing evidence. *Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 872, 228 U.S.P.Q. (BNA) 90, 97 (Fed. Cir. 1985); Jones v. Hardy, 727 F.2d 1524, 220 U.S.P.Q. (BNA) 1021 (Fed. Cir. 1984).*

The record contains no reference to this statutory presumption of validity, nor does it appear that the district court considered separately the validity of the three claims at issue. By merely holding that "defendants have proved by clear and convincing

evidence that the patent in suit (4,194,814) and each of its claims is invalid [*447] and therefore void," the district court improperly denied the '814 patent its statutory presumption of validity as to each claim.

The district court thought the examiner had been [**9] misled. Barnes-Hind argued and argues here that Bausch & Lomb (or rather its later acquired company Milton Roy) misled the examiner during prosecution. Appellees assert that "if the examiner had been correctly and forthrightly informed of Hager's and McCandless' opinions, the chemistry of the Brucker lens, and the teaching of the Caddell patent, he would not have issued the patent." The record, however, does not support this assertion.

The examiner did know of Hager's temporary refusal to execute the application during prosecution and, as discussed more fully *infra*, [HN2] a determination of nonobviousness is based, *inter alia*, on the opinion of a hypothetical person of ordinary skill in the art, not on the inventors' opinion. The weight to be attached to Hager's refusal cannot be exaggerated as the court below has done without clear error in view of Hager's self interest as an employee of a competitor and his later change of position. Instances of inventors refusing even to cooperate in obtaining issuance of a patent to be owned by an assignee are common and machinery is provided in [**10] *37 C.F.R. § 1.47* to deal with them. Section 1.47 provides that either a joint inventor or a proper assignee may file the application without the consent or signature of the inventor, just so the oath or declaration is accompanied by a petition including proof of pertinent facts. It is clear, therefore, that the PTO does not allow the inventor to erect that type of obstacle to obtaining patent protection. Such forethought is necessary, as otherwise an inventor's changed self interest might nullify a proper assignment. The district court's heavy reliance on Mr. Hager's assertions, if persisted in, would allow a co-inventor another chance at sabotage if the first effort has failed.

Finally, the examiner, who with the deference we owe governmental officials we assume has some expertise in interpreting the references and some familiarity with the level of skill in the art, *American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359, 220 U.S.P.Q. (BNA) 763, 770* (Fed. Cir.), *cert. denied, 469 U.S. 821, 105 S. Ct. 95, 83 L. Ed. 2d 41 (1984),* did have the Brucker and Caddell patents before him. Barnes-Hind's "misleading the examiner" contention [**11] is insufficiently supported to overcome the presumption of validity.

As a final matter, we recognize, as the district court did not, that [HN3] when the prior art before the court is the same as that before the PTO, the burden on the party asserting invalidity is more difficult to meet. *American Hoist, 725 F.2d at 1359, 220 USPQ at 770.*

2. *Graham Findings*

[HN4] Obviousness under *35 U.S.C. § 103* is a question of law based on the underlying factual inquiries set forth in *Graham v. John Deere Co., 383 U.S. 1, 17, 15 L. Ed. 2d 545, 86 S. Ct. 684, 148 U.S.P.Q. (BNA) 459 (1966):* (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art; and (4) objective evidence of secondary considerations. *See, e.g., Loctite, 781 F.2d at 872, 228 USPQ at 97-98.*

The *Loctite* court further stated:

> [**12] [HN5] In patent cases, the need for express *Graham* findings takes on an especially significant role because of an occasional tendency of district courts to depart from the Graham test, and from the statutory standard of obviousness that it helps determine, to the tempting but forbidden zone of hindsight. Thus we must be convinced from the opinion that the district court actually applied *Graham* and must be presented with enough express and necessarily implied findings to know the basis of the trial court's opinion.

Id., 228 U.S.P.Q. at 98.

Here, as in *Loctite* and in *Jones*, we are not convinced that the district court applied the *Graham* findings. Instead, it found Mr. Hager's opinion that the subject [*448] matter was obvious "most indicative of the obviousness of the invention." This was legal error.

Unlike the district court, we have the benefit of the very clear exposition of the law in *Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 454, 227 U.S.P.Q. (BNA) 293, 297-98 (Fed. Cir. 1985):*

> [**13] [HN6] The issue of obviousness is determined entirely with reference to a *hypothetical* "person having ordinary skill in the art." It is only that hypothetical person who is presumed to be aware of all the pertinent art. The actual inventor's skill is irrelevant to this inquiry, and this is for a very important reason. The

> statutory emphasis is on a person of *ordinary* skill. Inventors, as a class, according to the concepts underlying the Constitution and the statutes that have created the patent system, possess something -- call it what you will -- which sets them apart from the workers of *ordinary* skill, and one should not go about determining obviousness under § 103 by inquiring into what *patentees* (i.e., inventors) would have known or would likely have done, faced with the revelation of references. [Emphasis in original.]

In this regard then, the district court erred at least three times: it relied too heavily on the alleged opinion of one who was an inventor and patentee, and misused that opinion as a substitute for determining the level of skill of the hypothetical person of ordinary skill and what that person would have been able to do when in possession [**14] of the prior art, the scope and contents of which the court should also have determined.

The court also engaged in improper hindsight analysis to conclude the '814 patent would have been obvious. The court essentially adopted Barnes-Hind's argument that "the concept of forming ridgeless depressions having smooth rounded edges using a laser beam to vaporize the material is explicitly disclosed in the Caddell patent. *This is exactly the same process claimed in the patent-in-suit and practiced by the plaintiff.*"

Barnes-Hind selected a single line out of the Caddell specification to support the above assertion: "one way in which this [forming ridgeless depressions] can be achieved is to use a laser with high enough intensity to vaporize the plate material without melting it." Col. 5, lines 53-54. This statement, however, was improperly taken out of context. As the former Court of Customs and Patent Appeals held:

> [HN7] It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion [**15] of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art.

In re Wesslau, 53 C.C.P.A. 746, 353 F.2d 238, 241, 147 U.S.P.Q. (BNA) 391, 393 (CCPA 1965); see also In re Mercier, 515 F.2d 1161, 1165-66, 185 U.S.P.Q. (BNA) 774, 778 (CCPA 1975).

A full appreciation of Caddell's statement requires consideration of the immediately following sentences in the same paragraph and the paragraph after that. Viewed in that context, it is apparent that Caddell's ideal printing plate would have no ridges around the depression. The use of a high intensity laser is offered as a possible means to achieve the goal but is limited by several disadvantages. To overcome these disadvantages, Caddell suggests the use of a special class of polymer that forms ridgeless depressions. A complete reading demonstrates quite clearly that Caddell is setting up a strawman and pointing out its disadvantages to highlight the advantages of Caddell's invention, that special class of polymers. The district court improperly viewed an isolated line in Caddell in light of the teaching of the '814 patent to hold for obviousness. [**16] This is improper hindsight analysis.

The district court also failed to consider the Caddell reference in its entirety and thereby ignored those portions of the reference that argued against obviousness. *W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1550, 220 U.S.P.Q. (BNA) 303, 311 (Fed. Cir. 1983), cert. denied, 469 U.S. 851, 105 S. Ct. 172, 83 L. Ed. 2d 107 (1984).* [*449] Caddell compared the ridge formation of his special class of polymers against, *inter alia*, Lucite, a copolymer composed of ethyl acrylate with methylmethacrylate -- very similar to the chemical referred to in the '814 patent -- and found that *only* his special class formed depressions without ridges. Thus, Caddell actually taught away from laser etching of soft contact lenses.

As further evidence of obviousness, the district court relied on Dr. Brucker's experiments in laser marking contact lenses. This too was error, in this case clearly erroneous factual error. The record does not support, indeed it contradicts, the supposition that Dr. Brucker had engaged in laser marking of soft contact lenses at the time of the present invention. On page [**17] 385 of the Appendix, in reply to Mr. Calimafde's question "when did Continuous Curve begin to experiment with laser marking of soft contact lenses?", Dr. Brucker replied "I believe it was in '79 -- '79, '80, somewhere in that area." The filing date of the '814 patent was November 10, 1977. Brucker's 3,833,786 patent for a method of fenestrating (putting windows in) contact lenses applies according to its claims to such lenses, both soft and hard. However, the record reflects that the need for such fenestration was as a mode of escape for fluid accumulating between the lens and the eye. Such a need does not exist respecting the soft lenses, the principal

subject of the claims in suit, of which claim 2 is expressly limited to soft lenses. They, being hydrophilic, absorb the fluid.

In sum, the district court improperly determined the '814 patent was obvious: it failed to make the *Graham* inquiries, it improperly focused on what was obvious to the inventor, it engaged in hindsight analysis, and it considered evidence that was not prior art. This court, as an appellate court, may not make the required *Graham* factual findings, and must therefore remand that determination to [**18] the district court. The district court should not ignore the four-part analysis the authorities require.

a. *The scope and content of prior art*

[HN8] To determine whether a reference is within the scope and content of the prior art, first determine if the reference is within the field of the inventor's endeavor. If it is not, then next consider whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. *In re Richard M. Deminski, 796 F.2d 436,* slip op. at 9 (Fed. Cir. 1986); *Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1535, 218 U.S.P.Q. (BNA) 871, 876 (Fed. Cir. 1983). Orthopedic Equipment Co., Inc. v. United States, 702 F.2d 1005, 1008-11, 217 U.S.P.Q. (BNA) 193, 196-97 (Fed. Cir. 1983)* focused on the claims in suit, the art the PTO applied to the claims, and the nature of the problem confronting the inventor. Further, the art must have existed as of the date of invention, presumed to be the filing date of the application until an earlier date is proved.

b. *The differences* [**19] *between the claimed invention and the prior art*

[HN9] The court must view the claimed invention *as a whole. See, e.g., Jones, 727 F.2d at 1527-28, 220 USPQ at 1024.* We add, as a cautionary note, that the district court appeared to distill the invention down to a "gist" or "core," a superficial mode of analysis that disregards elements of the whole. It disregarded express claim limitations that the product be an ophthalmic lens formed of a transparent, cross-linked polymer and that the laser marks be surrounded by a smooth surface of unsublimated polymer. *See also, ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 221 U.S.P.Q. (BNA) 929 (Fed. Cir. 1984).*

c. *Level of ordinary skill in the art*

In *Environmental Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 697, 218 U.S.P.Q. (BNA) 865, 868-69 (Fed. Cir. 1983), cert. denied, 464 U.S. 1043, 79 L. Ed. 2d 173, 104 S. Ct. 709, 224 U.S.P.Q. (BNA) 520 (1984),* the court listed [**20] [HN10] six factors relevant to a determination of the level of ordinary skill: educational level of the inventor, type of problems encountered in the art, prior art solutions, rapidity of innovation, sophistication [*450] of technology, and educational level of active workers in the field. As to educational level of the inventor, *see Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 227 U.S.P.Q. (BNA) 293 (Fed. Cir. 1985); Orthopedic Equipment Co. v. All Orthopedic Appliances, 707 F.2d 1376, 1382, 217 U.S.P.Q. (BNA) 1281, 1285 (Fed. Cir. 1983)* ("Although the educational level of the inventor may be a factor in determining the level of ordinary skill in the art, it is by no means conclusive.")

d. *Objective indicia of obviousness*

Such [HN11] "secondary considerations," when present, must always be considered. *Stratoflex, 713 F.2d at 1538. See also Cable Electric Products, Inc. v. Genmark, Inc., 770 F.2d 1015, 1026-28, 226 U.S.P.Q. (BNA) 881, 887-88 (Fed. Cir. 1985).* Such evidence includes commercial success, long [**21] felt but unresolved needs, and failed attempts. *Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 895-96, 221 U.S.P.Q. (BNA) 669, 675* (Fed. Cir.), *cert. denied , 469 U.S. 857, 83 L. Ed. 2d 120, 105 S. Ct. 187 (1984).*

We shall vacate the trial court's opinion and remand for an obviousness determination consistent with this opinion.

3. *Infringement*

The parties narrowed the infringement issue for trial to the question whether the surface of Barnes-Hind lenses surrounding the laser mark is "smooth and unsublimated" or "unaffected." The district court concluded that "the laser-engraved depressions in the surface of the HYDROCURVE II lenses have been examined by scanning electron microscope. These photographs show that the surface of these lenses surrounding the laser mark are not 'smooth and unsublimated' or 'unaffected' as those terms were defined by plaintiff during the prosecution of the patent in suit." Appellant Bausch & Lomb argues on appeal that the trial court's approach of assessing smoothness at the very high levels of magnification obtainable by a SEM exceeds the level of smoothness required in the claims. We agree. [**22]

Because [HN12] the first step in determining infringement is claim construction, improper claim construction can distort the entire infringement analysis. *Moeller v. Ionetics, Inc., 794 F.2d 653,* slip op. at 7 (Fed. Cir. 1986). Such a distortion occurred below.

Disputed issues such as the meaning of the term "smooth," should be construed by resort to extrinsic evidence such as the specification, other claims, and the prosecution history. Here, resort to the specification

clearly demonstrates that "smooth" meant that "the edges of the craters neither inflame nor irritate the eyelid of the lens wearer * * *. The markings provided on the lens surface in accordance with this invention * * * are not perceived by the lens wearer * * *." The prosecution history supports this construction. A reading of the amendment and its accompanying remarks demonstrates that smooth means the absence of a ridge that "would scratch either the eye or eyelid and would lead to infection." There is no indication that smooth means absolutely ridge-free. (This review of the prosecution history also [**23] leads us to disagree with Barnes-Hind's final argument that the prosecution history estops Bausch & Lomb from asserting infringement against the allegedly ridged HYDROCURVE lens.) Testimony from Dr. Mandell, Bausch & Lomb's expert in the field of contact lenses, indicates that to a person of ordinary skill in the art, smooth would mean an absence of "roughness or significant elevation" so that a wearer "would not feel it with the [eye]lid." Further, there is testimony that a person of ordinary skill in the art would use an optical microscope, not an SEM, to gauge the relative smoothness of an etched contact lens.

We hold that smooth means smooth enough to serve the inventor's purposes, *i.e.*, not to inflame or irritate the eyelid of the wearer or be perceived by him at all when in place. Accordingly, we vacate the district court's conclusion that the surface of the HYDROCURVE lenses are not smooth or unaffected, and remand for a determination of infringement based on the proper construction of and proper test for smooth.

[*451] *Conclusion*

We vacate the district court's determination that the '814 patent is invalid and remand for a reconsideration of validity in [**24] light of the presumption of validity and the *Graham* findings on obviousness. We further vacate the decision of noninfringement and remand for proper claim construction and infringement analysis.

VACATED AND REMANDED.

LEXSEE 988 F2D 1181

IN RE VAN GEUNS

91-1088

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

988 F.2d 1181; 1993 U.S. App. LEXIS 4331; 26 U.S.P.Q.2D (BNA) 1057

March 10, 1993, Decided

PRIOR HISTORY: [**1] Appealed from: U.S. Patent & Trademark Office. Board of Patent Appeals & Interferences

DISPOSITION: AFFIRMED.

CASE SUMMARY:

PROCEDURAL POSTURE: Appeal from a decision of the Patent and Trademark Office's Board of Patent Appeals and Interferences holding that the claims of plaintiff's application that had been designated as corresponding to the interference count were unpatentable for obviousness under *35 U.S.C.S. § 103.*

OVERVIEW: Plaintiff filed a patent application with the U.S. Patent & Trademark Office (PTO), which provoked an interference count, as plaintiff copied claims from another applicants' information. The PTO determined that plaintiff's claims corresponded substantially to the count because they defined the same patentable invention. The Board of Patent Appeals and Interferences held the claims of plaintiff's application that had been designated as corresponding to the interference count were unpatentable for obviousness under *35 U.S.C.S. § 103.* On appeal, the court affirmed, reasoning when a party to an interference raised an issue of patentability, PTO's rules mandated that the claims were used to determine patentability. The court further determined that where a party did not timely contest the designation of claims, there was in effect a concession that all of the designated claims would have been anticipated or made obvious if the count were actually prior art.

OUTCOME: The decision of the board was affirmed because plaintiff's failure to timely contest the designation of claims was in effect a concession that all of the designated claims would be anticipated or made obvious if the count were actually prior art.

LexisNexis(R) Headnotes

Patent Law > U.S. Patent & Trademark Office Proceedings > Interferences > Patentability & Priority Determinations
Patent Law > Claims & Specifications > Claim Language > General Overview
[HN1] It is axiomatic that the claims define the invention which an applicant believes is patentable. Although claims of one or more of the parties may be identical to the count of an interference, the count is not a claim to an invention. The count of an interference is merely the vehicle for contesting the priority of invention and determining what evidence is relevant to the issue of priority.

Patent Law > U.S. Patent & Trademark Office Proceedings > Interferences > Patentability & Priority Determinations
[HN2] The U.S. Patent and Trademark Office (PTO) Board of Patent Appeals and Interference's rules provide that when the PTO considers patentability in an interference proceeding it will rule on the patentability of a claim.

Patent Law > U.S. Patent & Trademark Office Proceedings > Interferences > Patentability & Priority Determinations
Patent Law > Claims & Specifications > Claim Language > Preambles

[HN3] See 37 C.F.R. § 1.641.

Patent Law > U.S. Patent & Trademark Office Proceedings > Interferences > Patentability & Priority Determinations
Patent Law > Claims & Specifications > Claim Language > Preambles
[HN4] When a party to an interference raises an issue of patentability, 37 C.F.R. § 1.633(a) emphasizes that the claims are used to determine patentability. The rule states that a party may file a motion for judgment on the ground that an opponent's claim corresponding to a count is not patentable.

Patent Law > Nonobviousness > Elements & Tests > General Overview
Patent Law > Jurisdiction & Review > Standards of Review > General Overview
[HN5] Obviousness under *35 U.S.C.S. § 103* is a legal conclusion which the court reviews de novo, while the court reviews underlying factual findings under the clearly erroneous standard.

Patent Law > Claims & Specifications > Description Requirement > General Overview
Patent Law > U.S. Patent & Trademark Office Proceedings > Reissues > General Overview
Patent Law > U.S. Patent & Trademark Office Proceedings > Interferences > General Overview
[HN6] In the patentability context, claims are to be given their broadest reasonable interpretations. Moreover, limitations are not to be read into the claims from the specification.

Patent Law > U.S. Patent & Trademark Office Proceedings > Interferences > Patentability & Priority Determinations
Trademark Law > Protection of Rights > Registration > Federal Registration
Patent Law > Claims & Specifications > Claim Language > General Overview
[HN7] When an interference is declared between a patent and an application, the U.S. Patent & Trademark Office Board of Patent Appeals & Interferences' rules require that all claims in the application and patent which define the same patentable invention as a count shall be designated to correspond to the count.

Patent Law > Nonobviousness > Elements & Tests > Prior Art
Patent Law > Claims & Specifications > Claim Language > General Overview
Patent Law > U.S. Patent & Trademark Office Proceedings > Interferences > General Overview
[HN8] See *37 C.F.R. § 1.601(n)*.

Patent Law > Nonobviousness > Elements & Tests > Prior Art
Patent Law > Anticipation & Novelty > Elements
Patent Law > U.S. Patent & Trademark Office Proceedings > Interferences > General Overview
[HN9] The U.S. Patent and Trademark Office Board of Patent Appeals and Interference's rules permit a party to contest the designation of particular claims as corresponding to a count. If a party does not timely contest the designation of claims, there is in effect a concession that all of the designated claims would be anticipated or made obvious if the count were actually prior art. Thus, if the actual prior art reference anticipates the subject matter of the count, that is, the prior art reference has elements corresponding to each and every limitation in the count, all claims that are designated as corresponding to that count would be unpatentable for anticipation or obviousness.

Patent Law > Nonobviousness > Elements & Tests > Prior Art
Patent Law > Anticipation & Novelty > Elements
Patent Law > Claims & Specifications > Claim Language > General Overview
[HN10] Where the rejection is for obviousness, the prior art and the subject matter of the count are not the same that is, the prior art reference does not have elements corresponding to each and every limitation in the count. In such case, the claims designated as corresponding substantially to the count are not necessarily the same invention as the prior art, anticipated or made obvious by that art even though they are conceded to be the same invention as the count.

Patent Law > U.S. Patent & Trademark Office Proceedings > Interferences > Patentability & Priority Determinations
Patent Law > U.S. Patent & Trademark Office Proceedings > Appeals
Patent Law > Claims & Specifications > Claim Language > General Overview
[HN11] When either the examiner-in-chief (EIC) or a party raises an issue of patentability, arguments are directed first to the EIC. After a decision by the EIC, each party is then entitled to a final hearing by the U.S. Patent & Trademark Office Board of Patent Appeals & Interferences on the issue of patentability. The interference rules do not specify whether a party may argue the patentability of claims separately to the EIC and the board. However, the procedures for considering patentability in an interference proceeding essentially parallel the usual ex parte patentability prosecution and appeal procedures.

Patent Law > Claims & Specifications > Claim Language > Representative Claims
Patent Law > U.S. Patent & Trademark Office Proceedings > Interferences > Patentability & Priority Determinations
[HN12] A party to an interference proceeding should be permitted to argue separately the patentability of claims designated as corresponding substantially to a count, just as a party would be permitted to do in an ex parte prosecution and appeal. Of course, if a party chooses not to argue the claims separately, they would stand or fall together.

Patent Law > Claims & Specifications > Claim Language > General Overview
[HN13] See *37 C.F.R. § 1.192(c)(5).*

COUNSEL: Jack E. Haken, U.S. Philips Corporation, of Tarrytown, New York, argued for appellant.

Fred E. McKelvey, Solicitor, Office of the Solicitor, of Arlington, Virginia, argued for appellee. With him on the brief was Lee E. Barrett, Associate Solicitor.

JUDGES: Before ARCHER, PLAGER, and RADER, Circuit Judges.

OPINIONBY: ARCHER

OPINION: [*1183] ARCHER, Circuit Judge.

Johannes R. Van Geuns appeals from the September 25, 1990 decision of the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (board) in Interference No. 101,855, involving U.S. Patent No. *4,587,504* issued to Ian J. Brown et al. and U.S. Patent Application Serial No. 657,636 filed by Johannes R. Van Geuns. The board held that the claims of Van Geuns' application that had been designated as corresponding to the interference count were unpatentable for obviousness under *35 U.S.C. § 103* (1988). We affirm.

I.

The interference count is directed to a superconducting magnet. Superconducting magnets produce intense magnetic fields that, inter alia, may be used in Nuclear Magnetic Resonance (NMR) and Magnetic [**2] Resonance Imaging (MRI) apparatus. The count, however, is not limited to NMR or MRI apparatus.

To provoke the interference, Van Geuns, who became the senior party, copied claims 1-4, 9, and 10 from Brown's patent into his application as claims 42-47. Van Geuns' claim 42 and Brown's claim 1 correspond exactly to the count, see *37 C.F.R. § 1.601(f)* (1987), which is defined as follows:

> A magnet assembly comprising a first superconducting coil assembly defining a working volume and adapted to generate a first magnetic filed in said working volume; and a second superconducting coil assembly adapted to generate a second magnetic field, said second superconducting coil assembly being electrically connected in series with said first superconducting coil assembly, wherein said first and second superconducting coil assemblies are each adapted to generate magnetic fields whose corresponding components are of substantially the same order of magnitude, said assemblies being arranged such that a resultant, uniform magnetic field is generated in said working volume, and said second magnetic field opposes said first magnetic field externally of said magnet assembly.

The PTO determined that [**3] Van Geuns' claims 22-41 and 43-47 correspond substantially to the count because they define the "same patentable invention." *37 C.F.R. § 1.601(f).*

Brown filed preliminary motions in the period provided; Van Geuns did not. See 37 C.F.R. § § 1.633, 1.636. At the time of the examiner-in-chief's (EIC) decision on the preliminary motions, the EIC moved sua sponte under 37 C.F.R. § § 1.610(e) and 1.633(a) for judgment on the ground that the subject matter of the count was unpatentable under *35 U.S.C. § 103.* Notice was given to the parties pursuant to 37 C.F.R. § 1.640(d) that judgment would be entered unless they showed cause why such action should not be taken. Both parties responded to the notice, took testimony, filed briefs, and appeared before the board for oral hearing.

The board found the subject matter of the count unpatentable for obviousness under section 103 because of Japanese published application 52-90293 (the Japanese reference) taken alone or in view of German published patent specification 26 46 467 (the German reference). The board [*1184] went on to hold that "all of the claims of the parties which correspond [to the count] stand or fall [**4] therewith." Thus, Van Geuns' claims 22-47, which had been designated as corresponding to the count, were deemed to be unpatentable for obviousness.

II.

A. As a preliminary matter, we note that the board held that the subject matter of the count in the interference proceeding is unpatentable under *35 U.S.C. § 103.* [HN1] It is axiomatic that the claims define the invention which an applicant believes is patentable. See *Sealed Air Corp. v. United States Int'l Trade Comm'n, 68 C.C.P.A. 93, 645 F.2d 976, 985, 209 USPQ 469, 477 (CCPA 1981)* (citing *Cimiotti Unhairing Co. v. American Fur Refining Co., 198 U.S. 399, 49 L. Ed. 1100, 25 S. Ct. 697 (1905)); 35 U.S.C. § 112* (1988). Although claims of one or more of the parties may be identical to the count of an interference, the count is not a claim to an invention. *Case v. CPC Int'l, Inc., 730 F.2d 745, 749, 221 USPQ 196, 200 (Fed. Cir. 1984).* The count of an interference is merely the vehicle for contesting the priority of invention and determining what evidence is relevant to the issue of priority. *Squires v. Corbett, 560 F.2d 424, 433, 194 USPQ 513, 519 (CCPA 1977);* [**5] see also Case, *730 F.2d at 749, 221 USPQ at 200.*

[HN2] The PTO rules provide that when the PTO considers patentability in an interference proceeding it will rule on the patentability of a claim. For example, if an EIC raises an issue of patentability during interference, the PTO's rules provide:

> [HN3] During the pendency of an interference, if the examiner-in-chief becomes aware of a reason why a claim corresponding to a count may not be patentable, the examiner-in-chief may notify the parties of the reason and set a time within which each party may present its views. After considering any timely filed views, the examiner-in-chief shall decide how the interference shall proceed.

37 C.F.R. § 1.641 (emphasis supplied); see also *Miller v. Chester, 13 USPQ2d 1387* (Bd. Pat. App. & Int. 1989) (the board rejected as unpatentable particular claims corresponding to an interference count), aff'd, *906 F.2d 1574, 15 USPQ2d 1333 (Fed. Cir. 1990).* Similarly, [HN4] when a party to an interference raises an issue of patentability, 37 C.F.R. § 1.633(a) emphasizes that the claims are used [**6] to determine patentability. The rule states that a party may file a "motion for judgment on the ground that an opponent's claim corresponding to a count is not patentable." 37 C.F.R. § 1.633(a) (emphasis supplied).

Although the board properly should determine patentability with reference to a specific claim or claims, in this case Van Geuns' claim 42 corresponds identically to the count. We therefore view the board's decision as a rejection of that claim.

B. [HN5] Obviousness under *35 U.S.C. § 103* is a legal conclusion which we review de novo, while we review underlying factual findings under the clearly erroneous standard. *In re Woodruff, 919 F.2d 1575, 1577, 16 USPQ2d 1934, 1935 (Fed. Cir. 1990).*

Van Geuns' claim 42 recites a magnet assembly with a "uniform magnetic field." The board found that the Japanese reference disclosed a magnet assembly with a substantially uniform magnetic field, varying no more than 10 percent. Van Geuns does not disagree with this finding. Instead, Van Geuns argues that the uniform magnetic field limitation of claim 42 must be interpreted in light of the specification [**7] and the understanding of persons skilled in the NMR and MRI art. Van Geuns then contends that the Japanese reference does not make the invention of claim 42 obvious because it does not teach the level of magnetic field uniformity required for NMR imaging. The short answer is that claim 42 is not expressly limited to NMR or MRI apparatus. [HN6] In the patentability context, claims are to be given their broadest reasonable interpretations. *In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).* Moreover, limitations are not to be read into the claims from the specification. Id. Thus, Van Geuns cannot read an NMR limitation into [*1185] claim 42 to justify his argument as to the meaning of the "uniform magnetic field."

The board did not rest its decision as to the unpatentability of claim 42 entirely on the absence of an NMR limitation in the claim. The board discussed what one of ordinary skill in the NMR art would have ascertained from the Japanese reference. The board found the Japanese reference was analogous prior art which one of ordinary skill in the NMR art would consult. Relying on the expert testimony of Dr. Overweg, one of [**8] Brown's expert witnesses, the board also found that one of the ordinary skill would have known how to generate coil geometries to produce a magnetic field of any shape (e.g., a uniform field), would have known of the existence of algorithms and computer programs to aid in its design, and would have referred to the prior art to determine optimum current densities. We discern no error in these findings. n1 Therefore, even if the claim were limited to NMR or MRI apparatus, in light of what the Japanese reference teaches one of ordinary skill in the NMR or MRI art, the board did not err in concluding that claim 42 would have been obvious.

> n1 We note also that in his final hearing brief to the board, Van Geuns similarly asserted skill in the art as support for enablement of his claims under *35 U.S.C. § 112.* Although the enablement issue is not before us, it would be

> inconsistent to permit Van Geuns to rely on ordinary skill in the art, while precluding the board from relying on evidence of such skill.

[**9]

C. The board also held Van Geuns' remaining claims (claims 22-41 and 43-47) unpatentable because the patentability of all claims designated as corresponding tot he count stand or fall therewith. In urging that this holding is proper, the Commissioner cites three prior decisions in which the board has so held. See *Brooks v. Street, 16 USPQ2d 1374, 1378* (Bd. Pat. App. & Int. 1990); *Flehmig v. Giesa, 13 USPQ2d 1052, 1054* (Bd. Pat. App. & Int. 1989); *Kwon v. Perkins, 6 USPQ2d 1747, 1751* (Bd. Pat. App. & Int. 1988), aff'd on other grounds, *886 F.2d 325, 12 USPQ2d 1308 (Fed. Cir. 1989);* see also *Lamont v. Berguer, 7 USPQ2d 1580, 1582* (Bd. Pat. App. & Int. 1988). As a general proposition, the position of the Commissioner that claims designated as corresponding to a count stand or fall with the patentability of the subject matter of the count is overbroad. The rules for determining patentability in an interference proceeding and the scope of a party's admission when claims are designated as corresponding to the count must [**10] be considered.

[HN7] When an interference is declared between a patent and an application, the PTO rules require that "all claims in the application and patent which define the same patentable invention as a count shall be designated to correspond to the count." 37 C.F.R. § 1.606. The PTO rules define what is meant by the same patentable invention with the following example:

> [HN8] Invention A is the "same patentable invention" as an invention "B" when invention "A" is the same as *(35 U.S.C. 102)* or is obvious *(35 U.S.C. 103)* in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

37 C.F.R. § 1.601(n) (emphasis added).

[HN9] The PTO rules permit a party to contest the designation of particular claims as corresponding to a count. See 37 C.F.R. § § 1.633(c)(4), 1.637(c)(4)(ii). If a party does not timely contest the designation of claims, there is in effect a concession that all of the designated claims would be anticipated or made obvious if the count were actually prior art. n2 This follows from the above quoted definition of "same patentable invention." Thus, if the actual prior [**11] art reference anticipates the subject matter of the count (i.e., the prior art reference has elements corresponding to each and every limitation in the count), all claims that have been designated as corresponding to that [*1186] count would be unpatentable for anticipation or obviousness. See *37 C.F.R. § 1.601(n).*

> n2 Van Geuns objects that he could not timely contest the designation of claims 22-41 and 43-47 as corresponding to the count after the patentability issue was raised by the EIC. In view of our holding that the patentability of claims may be argued separately to the board, and our determinations that Van Geuns argued these claims separately to the board and the board found these arguments unpersuasive, we discern no prejudice.

The PTO attempts to take this logic one step further, essentially asserting that claims 22-41 and 43-47, which do not correspond exactly to the count, are unpatentable because the subject matter of the count has been determined to be unpatentable for obviousness. [HN10] Where the rejection [**12] is for obviousness, however, the prior art and the subject matter of the count are not the same i.e., the prior art reference does not have elements corresponding to each and every limitation in the count). In such case, the claims designated as corresponding substantially to the count are not necessarily the same invention as the prior art i.e., anticipated or made obvious by that art) even though they are conceded to be the same invention as the count. Thus, we conclude that a party to an interference, who has failed to timely contest the designation of claims corresponding to a count, has not conceded that claims corresponding to a count are anticipated or made obvious by the prior art when the subject matter of the count is determined to be unpatentable for obviousness. The PTO must determine, based on the actual prior art reference or references, whether claims not corresponding exactly to the count are unpatentable.

D. [HN11] When either the EIC or a party raises an issue of patentability, arguments are directed first to the EIC. See 37 C.F.R. § § 1.633(a), 1.636(a), 1.638(a), 1.641. After a decision by the EIC, each party is then entitled to a final hearing by the board [**13] on the issue of patentability. See 37 C.F.R. § § 1.654, 1.655(a)(3). The interference rules do not specify whether a party may argue the patentability of claims separately to the EIC and the board. See C.F.R. § § 1.601-1.690. However, the procedures for considering patentability in an interference proceeding essentially parallel the usual ex parte patentability prosecution and appeal procedures. We conclude that [HN12] a party to an interference proceeding should be permitted to argue separately the patentability of claims designated as

corresponding substantially to a count, just as a party would be permitted to do in an ex parte prosecution and appeal. Of course, if a party chooses not to argue the claims separately, they would stand or fall together. Cf. *37 C.F.R. § § 1.192(c)(5)*; n3 *In re King, 801 F.2d 1324, 1325, 231 USPQ 136, 137 (Fed. Cir. 1986).*

n3 *37 C.F.R. § 1.192(c)(5)* reads:

> [HN13] (5) Grouping of claims. For each ground of rejection which appellant contests and which applies to more than one claim, it will be presumed that the rejected claims stand or fall together unless a statement is included that the rejected claims do not stand or fall together, and in the appropriate part or parts of the argument under subparagraph (c)(6) of this section appellant presents reasons as to why appellant considers the rejected claims to be separately patentable.

[**14]

In this case, Van Geuns sought to argue his claims that correspond substantially to the count separately from his claim 42 that corresponds identically to the count. Van Geuns stated in his brief for final hearing that "claims 22-41 and 43-47 . . . have a scope which is different from that of the count." Van Geuns only distinguished these claims from the claim corresponding identically to the count based on a limitation to NMR or MRI apparatus; he did not further distinguish or argue them separately. As discussed above, the board properly found that even if the claims were limited to NMR or MRI apparatus, they would have been obvious in view of the Japanese reference. The board, therefore, properly determined that claims 22-41 and 43-47 were unpatentable.

For the foregoing reasons, the decision of the board is

AFFIRMED.

RELATED PROCEEDINGS APPENDIX

None.